IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

DYSON, INC., Plaintiff, v. MAYTAG CORPORATION, Defendant.	)	C.A. No. 06-654-GMS

DYSON, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION

YOUNG CONAWAY STARGATT & TAYLOR, LLP
C. Barr Flinn (No. 4092)
John W. Shaw (No. 3362)
Chad S.C. Stover (No. 4919)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
bflinn@ycst.com
jshaw@ycst.com
cstover@ycst.com

OF COUNSEL:

Chad S. Hummel
Kathrin A. Wanner
MANATT, PHELPS & PHILLIPS, LLP
7 Times Square
New York, New York 10036
(212) 790-4500

Attorneys for Plaintiff Dyson, Inc.

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(Continued)

Page

I. THE NATURE AND STAGE OF THE PROCEEDING

Four years ago, Plaintiff Dyson, Inc. ("Dyson") introduced a line of revolutionary, bagless, cyclonic vacuum cleaners in the United States market. In a now-iconic television commercial that kicked off Dyson's U.S. launch, company-founder James Dyson described the years of trial and error that ultimately led to his invention of the first vacuum cleaner that "doesn't lose suction." Dyson's advertising claim is amply supported because its vacuums do not lose suction. Their suction power remains constant during use, unlike that of other vacuum cleaners. Other vacuum cleaners (such as those made by Maytag) lose suction as dirt, dust and carpet fibers tend to clog the fine pores on internal filters and bags. Dyson has widely advertised this important point of difference, and Dyson vacuum cleaners have proven to be immensely popular with consumers.

Defendant Maytag Corporation, along with Hoover, Inc. and The Hoover Co. I, LP ("Maytag")[1] launched its own version of a bagless, cyclonic vacuum cleaner called the Hoover Fusion™ ("Fusion"), in the middle of 2005. Maytag either hoped to ride on Dyson's coat-tails, or to erode Dyson's exclusive and fully supported claim to No Loss of Suction, by claiming on product packaging and advertising that the Fusion also had No Loss of Suction. (See Declaration of Kathrin A. Wanner ("Attorney Decl."), Exhibits ("Exs.") A, G.) A tiny footnote to Maytag's No Loss of Suction claim on the Fusion vacuum product packages and the Maytag website stated: "Suction stays constant for up to 10 ounces of dirt, as tested by an independent laboratory using the ASTM International F558 test method and dirt composition comprised of 70% mineral dust, 20% cellulose dust and 10% fibrous material." (Id., Exs. C, G) For reasons discussed

[1] Maytag has represented to Dyson that Hoover, Inc. is the entity currently responsible for marketing the vacuums at issue in this litigation and that The Hoover Co. I, LP is the entity that has acquired the liability for the conduct at issue in this litigation. Based on these representations, the parties are seeking, through a stipulation and proposed amended complaint to

below, the footnote obfuscates with technical jargon and tiny typeface the essential point that Maytag's No Loss of Suction claim, at best, holds true for a short period of time under test conditions that do not reflect ordinary consumer use. Furthermore, a consumer survey commissioned by Dyson proves that few, if any, consumers read this footnote, much less understand it.

Shortly thereafter, Dyson challenged the Fusion No Loss of Suction claim before the National Advertising Division of the Council of Better Business Bureaus ("NAD"). The NAD is a widely-respected, advertising industry-funded arbitral forum that reviews national advertising for truthfulness and accuracy and determines whether advertising claims have been substantiated. Following a lengthy, contested proceeding in which both parties submitted extensive evidence, the NAD ruled in April 2006 that Maytag had not substantiated its No Loss of Suction claim and recommended that Maytag discontinue advertising that the Fusion has No Loss of Suction. (Attorney Decl., Ex. H at 33-34.)

Maytag publicly pledged to comply with the NAD's recommendations but ultimately displayed contempt for the NAD decision in both words and deeds. Around May 2006, Maytag launched a copycat vacuum to the Hoover Fusion, called the "Maytag Legacy." The new Maytag Legacy™ ("Legacy") is highly similar to the Fusion in styling, packaging, and marketing, and advertises the same No Loss of Suction claim found to be unsubstantiated by the NAD (along with the same inadequate fine-print disclaimer).[2] Moreover, Maytag took no steps to remove the No Loss of Suction claim from the packaging and advertising for the Fusion. Rather, it added language to the Fusion website that further obfuscated the claim, stating that

be filed within days, to add these parties as defendants in this case.

[2] As we discuss below, the Legacy loses suction even faster than the Fusion, based on tests by a leading independent laboratory.

"Vacuum Cleaner Suction Tests Do Not Represent Carpet Cleaning Ability" and that "No testing has established a correlation between suction performance and carpet cleaning in the home." (Attorney Decl., Ex. G.)[3]

Faced with Maytag's recalcitrance, Dyson lodged a compliance challenge with the NAD. (Attorney Decl., Ex. I.) On August 2, 2006, the NAD concluded that Maytag indeed had failed to comply with the NAD's previous decision, adding that Maytag's new language (described above) actually confused consumers by *contradicting* the performance benefit advertised by the "No Loss of Suction" claim. (Attorney Decl., Ex. J.) The NAD reiterated its recommendation that Maytag discontinue its "No Loss of Suction" claim. Because of Maytag's continuing refusal to comply, however, the NAD took the severe step of referring the matter to the Federal Trade Commission ("FTC") for potential enforcement under Section 5 of the FTC Act. (Id.)[4]

In June of 2006, Maytag's Vice President of Marketing, Dave Baker, revealed in a public interview with Advertising Age ("AdAge") magazine that Maytag intends to keep using the "No Loss of Suction" claim, in plain defiance of the NAD ruling. (Attorney Decl., Ex. K.) Mr. Baker told AdAge that "[w]e don't believe in the 'no loss of suction' claims." (Id.) Incredibly, Mr. Baker also told AdAge that Maytag would nevertheless keep advertising "No Loss of Suction" purely as "*a way to hit Dyson where they claim their superiority.*" (Id. (emphasis added).) Maytag thus signaled its clear intent to continue using the unsubstantiated "No Loss of

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[3] Maytag has represented to Dyson that it has ceased manufacturing the Fusion and the Legacy and is discontinuing its use of the "No Loss of Suction" advertising claim. However, retailers continue to sell both of these vacuums and Maytag continues to ship them as well. And, the "No Loss of Suction" claims can still be found on various retailers' websites as well as the boxes for the Fusion and the Legacy.

[4] This is not the first time Maytag has failed to comply with an NAD finding. In July of 2006, Bissell Homecare sued The Hoover Company for false advertising after attempting unsuccessfully to obtain Hoover's compliance with an NAD decision. Bissell Homecare, Inc. v. The Hoover Company, No. 1:06-CV-0464 (W.D. Mich. 2006).

Suction" claim purely to harm Dyson. Mr. Baker went on to say that Maytag would add a new statement telling consumers that "No Loss of Suction" is not correlated to vacuum cleaner cleaning performance in furtherance of its objective to "hit Dyson." (Id.)

Recognizing that the NAD itself could do no more, and that Maytag would proceed in defiance of the law until forced to stop, Dyson commissioned new product tests of the Fusion and Legacy to prepare for litigation. The tests, conducted by a leading lab under widely accepted international testing standards, were completed in August 2006. They show that the two Maytag products do, in fact, lose suction by about 35% under standard test conditions designed to be representative of consumer use. (Attorney Decl., Ex. O at ¶ 15.) Dyson also commissioned a consumer survey to test the effect of Maytag's footnote on consumer perception of the "No Loss of Suction" claim. The survey confirms that few consumers read the footnote, and few understand it. (Attorney Decl., Ex. P.)

Having diligently exhausted efforts to resolve this matter out of court through industry-recognized arbitration procedures, and having proven through product testing that the claims at issue are plainly false, Dyson filed a preliminary injunction motion in the United States District Court for the Southern District of New York on September 7, 2006, seeking emergency injunctive relief to prevent irreparable harm caused by Maytag's advertising and its ongoing refusal to comply with the NAD decision.

Since the filing of this action, Maytag has managed, through numerous delay tactics and misrepresentations to Dyson and the Court, to continue to profit from its false advertising conduct and to, in the process, irreparably damage Dyson's business and reputation. The action was transferred from the Southern District of New York to this Court based on Maytag's representation to the court that this case should be consolidated with the related action pending in

this Court, and that the Preliminary Injunction would be handled promptly upon transfer. (Attorney Decl., Ex. Q.) In December of 2006, Maytag told this Court that the cases should ***not*** be consolidated and that Dyson's Preliminary Injunction Motion should not be heard, once again causing delay in the resolution of the Motion. (Attorney Decl., Ex. R. at p. 41:7-11.)

Between December 2006 and March 2007, Maytag resisted all efforts to move this case forward and have the Preliminary Injunction Motion heard. At the scheduling conference before this Court on March 15, 2007, Maytag told this Court that Preliminary Injunction Motion was now moot because the Fusion was no longer being shipped and final Legacy shipments were going out in the spring. (Attorney Decl., Ex. S at p. 4:11-5:10.) However, this also did not prove to be true, as Dyson learned through interrogatory responses served by Maytag on April 13, 2007, that thousands of both Fusion and Legacy products were still going to be shipped to retailers with the No Loss of Suction claims, and that this would occur ***prior*** to the time that the Preliminary Injunction Motion is currently set to be fully briefed. (Attorney Decl., Ex. T.) Further, Dyson learned that, just during the six month period between September 2006 (when Dyson first filed this action seeking injunctive relief) and March 2007, Maytag has sold more than **$10,000,000** worth of Fusion and Legacy vacuums containing the No Loss of Suction claim. (Attorney Decl., Ex. T. at Response Nos. 3, 4.) Dyson also learned that stickering the remaining shipment and removing the No Loss of Suction claim from retail store displays could be done for a relatively minimal cost of $200,000. (Attorney Decl., Ex. T at Response No. 7(d).) Further, in response to an interrogatory asking precisely when any additional shipments of vacuums would be sent to retailers, Maytag did not provide a specific date and instead stated that the shipments would go out, and further advertising containing the false and unsubstantiated "No Loss of Suction" claim would be completed, "as of April 30, 2007." (Id., Response No. 7(b).) As such,

by engaging in substantial and calculated delay tactics, making misrepresentations to Dyson and to the Court, and refusing to directly respond to the interrogatories propounded by Dyson, Maytag sought to ensure that this Motion would not be resolved until ***after*** Maytag has made this "final" substantial shipment of vacuums containing the false advertising.

Perhaps most tellingly, when asked in recent interrogatories what if any steps Maytag has taken since the NAD non-compliance ruling to substantiate its advertising claims, Maytag simply objected to the interrogatory and refused to answer. An adverse inference in this regard is plainly appropriate. (Attorney Decl., Ex. T., Response No. 8.)

If Maytag is permitted to carry out its current plan to make these substantial shipments of products containing the false advertising that Dyson seeks to enjoin, Dyson will be irreparably harmed. As such, Dyson respectfully requests that the Court issue a Preliminary Injunction requiring Maytag to cease making these false claims in any of its advertising for these products, to sticker or otherwise remove the claims before making its remaining shipments, and to take commercially reasonable steps to remove these claims from inventory and displays currently in the retail channel and from retail websites.

II. SUMMARY OF ARGUMENT

Dyson respectfully submits this Memorandum in Support of its Motion for a Preliminary Injunction, along with the Declaration of Kathrin A. Wanner, and exhibits thereto, and a proposed order that sets forth the specific relief requested. This Court should issue a Preliminary Injunction because Maytag continues, despite numerous prior representations that the conduct would cease, to falsely claim in advertising for its Fusion and Legacy upright vacuum cleaners, that the vacuums provide "No Loss of Suction," *i.e.*, that the suction performance of these vacuum cleaners stays constant while consumers use them to clean their homes. Maytag's No Loss of Suction claim is false. Testing conducted by a leading independent laboratory proves

that both the Fusion and the Legacy *do* lose suction, by about 35%, as dust accumulates in the machines during conditions representative of ordinary use.

If permitted to continue, Maytag's false No Loss of Suction claim threatens irreparable harm to Dyson, which sells products that compete directly with the Fusion and the Legacy in the U.S. market for upright vacuum cleaners.

III. STATEMENT OF FACTS

A. Maytag's False And Misleading Campaign

Maytag is a leading manufacturer and marketer of vacuums in the United States, but Dyson has challenged Maytag's position in recent years with its innovative and revolutionary bagless cyclonic vacuum cleaners. In a desperate attempt to stem the tide of Dyson's success in challenging its position, Maytag has directly attacked Dyson's products by falsely claiming that Maytag's own vacuums have "No Loss of Suction." Maytag made these claims on its website, on packaging, and on the vacuums themselves. (Attorney Decl., Exs. A, B, F, and G.)

Currently, a small asterisk after the No Loss of Suction claim on Hoover Fusion and Maytag Legacy packaging (Attorney Decl., Exs. A, B) and the Maytag Legacy vacuum cleaner itself (Attorney Decl., Ex. F.) leads to a miniscule disclaimer stating that "Suction stays constant for up to 10 ounces of dirt, as tested by an independent laboratory using the ASTM International F558 test method and dirt composition comprised of 70% mineral dust, 20% cellulose dust and 10% fibrous material." (Attorney Decl., Ex. C, D; see also Ex. E.) As discussed below, Maytag indicated at some point that it would change its product packaging in two ways, first by adding a statement in bold print immediately beneath the "No Loss of Suction" claim that "Vacuum Cleaner Suction Tests Do Not Represent Carpet Cleaning Ability" and second, by adding a sentence to the disclaimer stating that "[n]o testing has established a correlation between suction performance and carpet cleaning ability in the home. Household results may vary." (Attorney

Decl., Ex. L.) These statements did at one time appear on the Hoover Fusion website. (Attorney Decl., Ex. G.) However, as the NAD found in its compliance decision (see Section C below), neither of these additions alters the plain, and false, meaning of the Maytag No Loss of Suction claim.[5]

B. Testing Confirms That Maytag's "No Loss of Suction" Claim Is False.

Contrary to Maytag's headline, bold-faced "No Loss of Suction" claim, the Fusion and Legacy do, in fact, lose suction. (See Attorney Decl., Ex O, ¶¶ 14-16.) This has been proven by tests conducted by Inter Basic Resources, Inc. ("IBR"), the country's only accredited testing laboratory for filtration and vacuum testing. (Id.) IBR is a leading, independent vacuum performance testing laboratory, and is relied on by every major manufacturer in the United States to test vacuum suction and other vacuum performance attributes. (Attorney Decl., Ex. O, ¶ 8.)

In tests of the Fusion and the Legacy commissioned by Dyson during the summer of 2006, IBR found that both the Fusion and the Legacy experience a significant loss of suction before the dust bin is full at 1200 grams of dust. (Attorney Decl., Ex. O, ¶¶ 15-16.) Thus, consumers using the units would experience a loss of suction before they would need to empty the dust bins, even for the very first time.

In an implicit concession that the Fusion and the Legacy do lose suction before their dust

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[5] The Owner's Manuals for the Fusion and Legacy further discredit Maytag's "No Loss of Suction" claim by conceding the machines will lose suction when used on fine particulates, such as face powder or corn starch. These manuals state on page 6 that "[i]t is recommended that the dirt cup be emptied before the dirt reaches the fill line . . . or after every use if preferred. **CAUTION: Very fine materials such as face powder or corn-starch, may seal the filter and cause loss of suction. When using the cleaner for this type of dust, empty the cup and clean the filters often."** (Attorney Decl., Ex. N) (bold in original) (the Hoover Fusion and Maytag Legacy vacuums both contain the same "Hoover Fusion" instruction manual). This disclosure is not made available to consumers prior to purchase.

bins are filled, Maytag's tiny, footnoted disclaimer[6] to the No Loss of Suction claim states in highly technical language that "Suction stays constant for up to 10 ounces of dirt, as tested by an independent laboratory using the ASTM International F558 test method and a dirt composition comprised of 70% mineral dust, 20% cellulose dust and 10% fibrous material."[7] As discussed below, a consumer survey conducted for Dyson shows that few, if any, consumers read or understand the disclaimer.

Unfortunately for Maytag, even in the unlikely circumstance that consumers could grasp the engineering jargon set out in the footnote (and a consumer survey shows the overwhelming majority do not), the ASTM F558 test referred to there is inapposite both to the main No Loss of Suction claim and to the purported disclaimer in the footnote. The ASTM F558 test measures only initial suction power of the vacuum cleaner -- not how suction changes as dust is vacuumed over time into the machine. (Attorney Decl., Ex. M.) In the ASTM F558 test, the vacuum cleaner is placed into a chamber, turned on, and suction power is measured as different orifice plates of varying diameters are placed onto the air intake to restrict air flow. (Id.) Not surprisingly, the ASTM standard itself states that "The test results allow the comparison of the maximum potential air power available for cleaning tasks . . . [and] *do not indicate the actual air power present during the cleaning process* due to the effect of the various tools in use and surfaces being cleaned." (Id., at §4.1 (emphasis added).)

Maytag's footnote reveals that it conducted ASTM test measurements, apparently by

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[6] On both the Legacy and Fusion packages, the disclaimer appears in tiny, low-contrast print, less than one inch from the bottom of the box. (See Attorney Decl., Ex. A, B; see also Ex. E.)

[7] ASTM International, originally known as the American Society for Testing and Materials (ASTM), is a voluntary standards development organization that produces technical standards for materials, products, systems, and services. See http://www.astm.org/cgi-bin/SoftCart.exe/ABOUT/aboutASTM.html?L+mystore+nazy7360+1156362319 (last visited Apr. 18, 2007).

adding an additional step that provides for the loading of dust and fiber into the machine.[8] While Maytag's tiny footnote purports to say that its ASTM tests show that suction remains constant "up to" 10 ounces of dirt,[9] the footnote says nothing about what happens thereafter – a precipitous decline in suction. The footnote, therefore, does not, by any means, cure or make true the broad and false message conveyed by the No Loss of Suction claim.

Ten ounces of dirt fills about 25% of the available dustbin capacity of the Fusion and Legacy vacuums. Yet over 23% of consumers who are shown the footnote and asked how much of the bin they think is filled by 10 ounces, believe 10 ounces is 75% or more of bin capacity. (See Attorney Decl., Ex. P ¶25.) The bins on each of the Legacy and Fusion units contain 2.7 liters of liquid volume, and during IBR's testing, they did not reach the "bin full" indicator until 1200 grams (42.4 ounces) of the IEC standard test dust mixture had been loaded. (Attorney Decl., Ex. O ¶¶ 15-16.)

As discussed in Section C, below, few actual consumers can pierce the technical jargon contained in Maytag's tiny footnote in order to discern that Maytag is saying that suction in the Legacy and Fusion remains constant only until the dust bins are at roughly 25% of capacity (283 grams out of 1200 grams total). This is because Maytag never explains this critical qualification to consumers in prominent, easy-to-understand language. Nor does Maytag prominently qualify the headline No Loss of Suction claim by disclosing that its products may experience a significant decline of suction as they progress to fill the remaining bin capacity. IBR's tests for Dyson show that suction declines by about 35% during this period. (Attorney Decl., Ex. O ¶¶15-

[8] This testing was also carried out by IBR. Dyson has no quarrel with IBR's execution of the test *per se*, but rather Maytag's reliance on its results to make a No Loss of Suction claim in advertising.

[9] Maytag's counsel has claimed that this is equivalent to a "single use." (Attorney Decl., Ex. L.) Product instructions do not require the bin to be emptied after each use. (Attorney Decl., Ex. N.)

16.)

In contrast to the modified ASTM F558 test relied on by Maytag, Dyson commissioned testing under an industry-consensus standard test developed by the International Electrotechnical Commission ("IEC"),[10] which is specifically designed to measure the change in suction over time as dust is loaded into the machine. (Attorney Decl., Ex. O ¶11.) This standard, Part 2.9 of IEC 60312 ("Reduction in maximum air flow with a partly filled dust receptacle"), provides for the measurement and comparison of changes in suction as dust is fed into vacuum cleaners under standardized conditions designed to be representative of ordinary vacuum use. (Attorney Decl., Ex. O ¶¶10-11.) Major vacuum manufacturers and distributors (such as Maytag), representatives from which have been participating members of the IEC 60312 committee that developed the test (Attorney Decl., Ex. O ¶3), are intimately familiar with this method.

Independent testing by IBR using the IEC 60312, Part 2.9 standard shows that the suction performance of the Fusion and the Legacy drop by about 35%. (Attorney Decl., Ex. O ¶¶15-16.) In IBR's tests, three units of each of the Legacy and Fusion vacuum cleaners were tested under IEC standard test conditions by measuring suction under conditions of steady dust loading until the bins of each had been completely filled with a standard test dust mixture, in accordance with IEC standards. (Id.) The test results demonstrate a significant decline in suction for all of the tested units. (Id.).

Consumers reading the No Loss of Suction claim on the Maytag boxes will reasonably expect suction of the Fusion and Legacy to remain constant during use. The footnote does not disclose to them that suction drops substantially. A consumer who uses the Fusion or Legacy

[10] The IEC is "the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies." See http://www.iec.ch/about/mission-e.htm (last visited Aug. 24, 2006).

expecting No Loss of Suction will be sorely disappointed.

C. The No Loss of Suction Claim Is Also Misleading, Even When Read Along With The Footnoted Disclaimer.

A consumer survey conducted by noted consumer perception expert, Professor Michael Mazis of American University, shows that, while the No Loss of Suction claim is prominently displayed on the Hoover Fusion box, the accompanying disclaimer was neither recalled frequently nor comprehended often by consumers. (Attorney Decl., Ex. P ¶26.)

The survey took the form of a classic mall-intercept design. The universe for the study consisted of 208 recent upright vacuum cleaner purchasers or prospective upright vacuum cleaner purchasers. (Id. ¶10.) Interviews were conducted in eight shopping malls across the U.S. – with approximately one-fourth of the interviews taking place in each of the four U.S. Census regions. (Id.)

Survey respondents who qualified for the study were shown the Hoover Fusion box, and instructed to read all of the information on the box as though they were considering purchasing an upright vacuum cleaner. (Id. ¶14.) The box was then removed and the interviewer asked respondents a series of questions regarding the box, beginning with an open-ended question: "Please tell me all of the information that you can remember reading on the vacuum box." (Id. ¶¶14-15.) Respondents were also asked "Do you or don't you recall seeing any information on the box about 'no loss of suction'?" (Id. ¶16.) Then, respondents were asked "Do you or don't you recall seeing a footnote with an asterisk at the bottom of the box?" (Id. ¶17.) Those responding affirmatively were asked, "What did the footnote at the bottom of the box say?" (Id.)

Interviewers then allowed respondents to see the Hoover Fusion box for a second time, asking respondent about their comprehension of the disclaimer. (Id. ¶18.) While the box was in front of the respondent, the interviewer said, pointing to the disclaimer:

> I'd like you to read this information in the footnote. When you are finished, please let me know, and I will have some questions for you about the information.
>
> The information in the footnote states that "suction stays constant for up to 10 ounces of dirt." What does this phrase mean to you? [and later] What else?

Finally, interviewers asked respondents to state what percentage of the dirt cup they thought 10 ounces of dirt would fill.

The results confirm that very few consumers saw, recalled, or understood the disclaimer. Of those consumers who reported recalling the "no loss of suction" message when asked the first open-ended question, only about 15% reported noticing the disclaimer. (Id. ¶23.) Even fewer consumers (about 4%) recalled key points regarding the message conveyed in the disclaimer. (Id.)

Moreover, when all consumers were asked to read the disclaimer, and were asked to indicate what percentage of the dirt cup they thought ten ounces of dirt would fill, most said either that they did not know (about 29%) or they estimated that 10 ounces of dirt would fill three-fourths or more of the dirt cup (about 23%). (Id.) Only 15.8% understood that 10 ounces of dirt would fill one-quarter or less of the dirt cup. (Id.)

D. The NAD Proceedings And Maytag's False Promise To Cease And Desist

The April 5, 2006 NAD decision states that Maytag had failed to substantiate its No Loss of Suction claim on the Fusion and recommends that Maytag discontinue the claim. (Attorney Decl., Ex. H.) The NAD reasoned that the No Loss of Suction claim "is a broad claim that reasonably communicates to consumers a performance attribute that occurs over time and with repeated use of their vacuum cleaners." (Id. at 33.) The NAD further concluded that the footnote used by Maytag did not adequately qualify this broad claim for several reasons.

First, the NAD was not persuaded that "there was sufficient correlation between the laboratory testing [relied on by Maytag] and consumer experience in the real world to support a 'No Loss of Suction Claim.'" (Id. at 34 (citing ASTM F558, part 4.1).) The NAD reasoned that, as discussed infra, the modified ASTM F558 test used by Maytag does not provide for measuring the suction of a vacuum cleaner in a dust-loaded condition. (Id.) Moreover, the NAD stated that it was not persuaded that Maytag's before-and-after version of the ASTM F558 test "was representative of real-world experience of consumers or a representative measure of how vacuum cleaners perform over time." (Id.)

Although it could have appealed the NAD decision, Maytag chose not to. Instead, in an Advertiser's Statement published along with the NAD decision, Maytag stated that it would comply with the NAD's recommendation. (Attorney Decl., Ex. H at p. 37.) But this has been nothing more than a ruse: in the ensuing months, Maytag failed to honor the NAD recommendation and continued marketing the Fusion with its "No Loss of Suction" claim. Compounding its noncompliance with the NAD recommendation, in or around late May 2006, Maytag launched a copycat vacuum to the Fusion, under the Maytag Legacy brand. The Legacy mimics the styling, packaging, and marketing of the Fusion, and bears an identical "No Loss of Suction" claim, complete with the same fine-print disclaimer. (Attorney Decl., Exs. B, D, F; see also Ex. E.) As discussed above, however, the Legacy performs even worse on industry standard tests of suction over time.

When Dyson learned of Maytag's actions, it initiated a compliance proceeding before the NAD, asking the NAD to take action under section 4.1 of the NAD procedures.[11] (Attorney

[11] Section 4.1 of the NAD Procedures states, "[A]t the behest of a challenger or a third party, [NAD] may request that the advertiser report back, within five (5) business days, on the status of the advertising at issue and explain the steps it has taken to bring the advertising into compliance

Decl., Ex. I.) After conducting its own investigation, the NAD issued its further decision, and a public press release, stating that Maytag had failed to comply with the NAD's prior recommendation. (Attorney Decl., Ex. J.) The NAD stated that because Maytag had refused to comply with its recommendation, it would refer the matter to the appropriate government agency for potential enforcement – in this case, the Federal Trade Commission, which has authority to curb deceptive advertising under Section 5 of the FTC Act, 15 U.S.C. § 45. *See* NAD Procedures, §4.1.C.(ii)(b)(2) (available at http://www.nadreview.org/Procedures.asp?SessionID=996260).

Making matters worse, Maytag told the national press that it not only intended to stick with the "No Loss of Suction" claim found unsubstantiated by the NAD, but that it would modify that claim in ways designed to injure Dyson. Maytag's Vice President of Marketing, Dave Baker, told AdAge magazine in an obscenity-laden interview that Maytag intended to keep advertising the "No Loss of Suction" claim despite the NAD decision. (Attorney Decl., Ex. K.) Mr. Baker, described by AdAge as "infuriated," told the magazine that "[w]e don't believe in the 'no loss of suction' claims," but added that Maytag would nevertheless keep advertising "No Loss of Suction" as "a way to hit Dyson where they claim their superiority." (Id.)

Maytag later indicated it would employ new language stating that "Vacuum Cleaner Suction Tests Do Not Represent Carpet Cleaning Ability" and that "No testing has established a correlation between suction performance and carpet cleaning ability in the home. Household results may vary." (Attorney Decl., Ex. L.) In a letter to counsel for Dyson's Canadian affiliate, Maytag stated that it believes these statements disclaim any "performance benefit" by "adequately communicat[ing] to consumers that Maytag's 'loss of suction' claim is not a

with the decision."

cleaning performance claim and is only for up to 10 ounces of dirt (*i.e.*, a single use),[12] not over time or with repeated use." (Id.)

In light of Maytag's complete reversal of its initial commitment to abide by the NAD recommendation and total disregard for the NAD's recommendation, made on two separate occasions, that Maytag discontinue its "No Loss of Suction" claims, Dyson's only remedy was to seek emergency injunctive relief, which it sought in the United States District Court for the Southern District of New York on September 7, 2006.

E. Maytag's Deliberate Delay of This Proceeding And Continuing Misrepresentations Regarding Ceasing the False Advertising

When Maytag moved to transfer this case to this Court, it urged that this case and the related case already pending before this Court should be consolidated, and expressly promised the New York Court: "the parties will be able to litigate Dyson's motion for a temporary injunction in Delaware promptly upon a transfer to that Court." (Attorney Decl., Ex. Q at p. 9, fn. 4) In December of 2006, Maytag then told this Court that the cases should ***not*** be consolidated once again causing delay in the resolution of the Motion. (Attorney Decl., Ex. R at 41:7-11.)

Between December 2006 and March 2007, Maytag resisted all efforts to move this case forward and have the Preliminary Injunction Motion heard. At the March 15 2007 scheduling conference, counsel for Maytag argued that Dyson's Preliminary Injunction Motion was moot because the two vacuum cleaners at issue in the motion are no longer being manufactured, and one of the vacuum cleaners – the **Hoover Fusion** – "is in fact no longer being shipped to retailers." (Attorney Decl., Ex. S at p. 4:12-13.) Thereafter, and in light of counsel's

[12] Maytag's assertion that 10 ounces equates with a "single use" is, to Dyson's knowledge, unsupported and confusing. The dustbin capacity of the Legacy and Fusion is well over that amount – about 42 ounces.

representations regarding Maytag's product, the parties agreed to meet and confer in good faith in an attempt to reach a private resolution of Dyson's Preliminary Injunction Motion. After the Scheduling Conference, on March 20, 2007, Dyson sent a draft limited settlement agreement to Maytag for its consideration. On March 23, 2007, Maytag's counsel sent a letter to counsel for Dyson refusing to engage in any substantive discussion regarding a private resolution of the motion and simply reiterating Maytag's position that the issue is moot due, in part, to the fact that "the Hoover Fusion is no longer being shipped to retailers." (Attorney Decl., Ex. U.)

On March 29, 2007 the Court conducted a telephonic status conference regarding the status of Dyson's Preliminary Injunction Motion. At the hearing, Dyson sought a limited 30(b)(6) deposition in advance of its Motion. Maytag resisted that request. The Court ordered Dyson to propound interrogatories in lieu of the deposition and Maytag promised to respond within seven days. (Attorney Decl., Ex. V at p. 19:15-20:21.) Subsequent to the status conference, Maytag insisted that they could not respond to Dyson's interrogatories (served on April 2, 2007) within the promised seven day response period and stated that they would respond on April 13, 2007, thereby further delaying the filing of Dyson's Motion. A Proposed Scheduling Order submitted to the Court on April 12, 2007, and so Ordered on that date, provides that Maytag would respond to the interrogatories on April 13, 2007, that Dyson would submit its renewed Preliminary Injunction Motion papers on April 20, 2007, that Maytag would submit its opposition papers on May 4, 2007, and that Dyson would submit its reply papers on May 11, 2007. (Attorney Decl., Ex. W.)

In its interrogatory responses served on April 13, 2007, Maytag revealed, contrary to its prior representations to the undersigned counsel and this Court, for the first time, that it does in fact plan to ship additional Hoover Fusion vacuums to retailers during the month of April (with

the offending literally false advertising claims which had previously been found false and unsubstantiated by the NAD). (Attorney Decl., Ex. T Response No. 7(b).) Maytag also revealed that it would be shipping up to 8,314 additional units of the Maytag Legacy vacuums to retailers during the month of April (which is equivalent to nearly 50% of the Maytag Legacy vacuums sold between the six month period between September 1, 2006 and March 31, 2007). [Id., Response Nos. 4, 7(b).] Further, in response to an interrogatory asking precisely when any additional shipments of vacuums would be sent to retailers, Maytag did not provide a specific date and instead stated that the shipments would go out, and further advertising containing the false and unsubstantiated "No Loss of Suction" claim would be completed, "as of April 30, 2007." [Id., Response No. 7(b).] Maytag further revealed that the estimated cost of stickering or otherwise removing the false advertising would be approximately $200,000. [Id., Response No. 7(d).]

IV. ARGUMENT

A. The Standards Applicable To Injunctive Relief In Lanham Act Cases Are Well-Settled.

Section 43(a) of the Lanham Act offers broad protection against false advertising. "The Lanham Act has the broad purpose of protecting competitors from a wide variety of misrepresentations of products and service." Am. Tel. and Tel. Co. v. Winback and Conserve Program, Inc., 42 F.3d 1421, 1433-34 (3d Cir. 1994) (vacating denial of injunctive relief and remanding for further consideration); see also Coll. Savings Bank v. Florida Prepaid Postsecondary Educ. Expense Bd., 131 F.3d 353, 357 (3d Cir. 1997) ("One of the main purposes of section 43 of the Lanham Act is to protect persons engaged in interstate commerce against unfair competition caused by false or misleading representations or advertising about goods, services, or commercial activities."). Congress specifically sought to provide a business

competitor of an advertiser a powerful legal tool to prevent consumer deception. Competitors "have the greatest interest in stopping misleading advertising, and a private cause of action under section 43(a) allows those parties with the greatest interest in enforcement, and in many situations with the greatest resources to devote to a lawsuit, to enforce the statute rigorously." Coca-Cola Co. v. Procter & Gamble Co., 822 F.2d 28, 31 (6th Cir. 1987); see also W.L. Gore & Assocs., Inc. v. Totes Inc., 788 F. Supp. 800, 808 (D. Del. 1992) ("Section 43(a) also recognizes that competitors can be injured by false advertising and it protects competitors from damage caused by such claims."). Accordingly, Section 43(a) vindicates a consumer's right to be told the truth, as well as a competitor's right to fair tactics in the marketplace. 4 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 27:25, at 27-43 (4th ed. 2004).

The law governing false advertising claims under the Lanham Act is well settled in this Circuit. To establish such a claim, a plaintiff must prove the following five elements:

> (1) The defendant has made false or misleading statements as to his product, or those of the plaintiff;
>
> (2) There was actual deception or at least a tendency to deceive a substantial portion of the intended audience;
>
> (3) The deception was material in that it is likely to influence purchasing decisions;
>
> (4) The advertised goods traveled in interstate commerce; and
>
> (5) There is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

See Warner-Lambert Co. v. Breathasure, Inc., 204 F.3d 87, 91-92 (3d Cir. 2000); Synopsis, Inc. v. Magma Design Automation, C.A. No. 05-701 (GMS), 2006 U.S. Dist. LEXIS 33751, at *8 (D. Del. May 25, 2006); Enzo Life Scis., Inc. v. Digene Corp., 295 F. Supp. 2d 424, 427 (D. Del. March 31, 2003). A claim of false advertising does not require proof of intent to deceive. See W.L. Gore Assocs., Inc., 788 F. Supp. at 805 ("When the advertising claim is false, the court

may grant relief on its own findings that the advertisements have a 'tendency to deceive.'"); The Stiffel Co. v. Westwood Lighting Group, 658 F. Supp. 1103, 1110-11 (D.N.J. 1987); Eli Lilly and Co. v. Roussel Corp., 23 F. Supp. 2d 460, 475 (D.N.J. 1998).

Under well-established Third Circuit law, preliminary injunctive relief is appropriate in Lanham Act cases where a plaintiff establishes: (1) reasonable probability of success on the merits; (2) irreparable injury absent relief; (3) the balance of equities between the parties favors granting the plaintiff relief; and (4) granting the injunctive relief will be in the public interest. See, e.g., Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co., 290 F.3d 578, 586 (3d Cir. 2002) (affirming grant of preliminary injunction against false advertising); W.L. Gore Assocs., Inc., 788 F. Supp. at 803 (granting preliminary injunction against false advertising); Upjohn Co. v. Riahom Corp., 641 F. Supp. 1209, 1221-22 (D. Del. 1986) (same). Dyson meets each part of this standard.

B. Dyson Is Likely To Succeed On The Merits Of Its Claims.

Given the proven, literal falsity of Maytag's "No Loss of Suction" claim, the likelihood that Dyson will succeed on its claims is high. Moreover, the NAD, a highly-respected neutral arbiter of advertising disputes, has already determined that Maytag's advertising claim of No Loss of Suction is unsubstantiated.

1. The "No Loss of Suction" Claim Is Literally False.

"A determination of literal falsity rests on an analysis of the message in context." Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone Poulenc Rorer Pharms., Inc., 19 F.3d 125, 129 (3d Cir. 1994); see also Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 946 (3d Cir. 1993). In analyzing whether Maytag's advertisements are literally false, the Court must first determine what the unambiguous claims made by the advertisement are, and second, whether those claims are false. See Novartis Consumer Health, Inc., 290 F.3d at 586. "A 'literally false'

message may be either explicit or 'conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.'" Id. at 586-87.

Maytag's advertised No Loss of Suction claim is literally false. As the NAD correctly concluded, the "'No Loss of Suction Claim'" is a broad claim that reasonably communicates to consumers a performance attribute that occurs over time and with repeated use of their vacuum cleaners." (Attorney Decl., Ex. H at p. 33.) The claim means that consumers will not experience a loss of suction during conditions of ordinary use and over time. Even if the court were to conclude that there is some ambiguity in the period of time for which the claimed "No Loss of Suction" holds true, the necessary implication of the claim is that suction will remain constant and undiminished so long as the consumer uses the vacuum under ordinary conditions, and not drop off after some arbitrary, intermediate point. Here, independent testing constitutes persuasive and reliable evidence demonstrating the falsity of Maytag's "No Loss of Suction" claim. Maytag's Fusion and Legacy vacuums do in fact lose suction by about 35%.

The tiny footnote is not part of the claim, but rather a failed attempt to qualify or disclaim the "No Loss of Suction" claim. It is so small that consumers do not see it prior to purchase. This Circuit and others have sensibly held that a literally false claim cannot be cured by means of a small-print footnote containing a disclaimer. See, e.g., Novartis Consumer Health, Inc., 290 F.3d at 598 ("We do not believe that a disclaimer can rectify a product name that necessarily conveys a false message to the consumer."); Liquid Glass Enters., Inc. v. Dr. ING. h.c.F. Porsche AG, 8 F. Supp. 2d 398, 405, n.5 (D.N.J. 1998) ("Disclaimers have frequently been found to be insufficient to avoid consumer confusion in the marketplace.") (citing Int'l Kennel Club of Chicago, Inc. v. Mighty Star, Inc., 846 F.2d 1079, 1093 (7th Cir. 1988) and United States

Jaycees v. Philadelphia Jaycees, 639 F.2d 134, 142 (3d Cir. 1981)). A footnote or disclaimer that "purports to change the apparent meaning of the claims and render them literally truthful, but which is so inconspicuously located or in such fine print that readers tend to overlook it, will not remedy the misleading nature of the claims." SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co., Inc., 906 F. Supp. 178, 182 (S.D.N.Y. 1995) (stating that such unacceptable disclaimers typically appear "in small size print near the bottom of the document and either contradict, clarify, or change the meaning of the main claim of the advertisement"); see also Johnson & Johnson-Merck Consumer Pharms. Co. v. The Procter & Gamble Co., 285 F. Supp. 2d 389, 392 (S.D.N.Y. 2003) (stating that "The bottom line is that a statement, although literally true [in light of a footnote], can for all practical purposes, convey a false message.") These conclusions are particularly apt in this instance, given that the consumer survey conducted by Dr. Mazis overwhelmingly demonstrates that very few people read the tiny disclaimer on the Hoover Fusion package.

Even for the handful of consumers who actually read the disclaimer, the text of the footnote used by Maytag obfuscates the key point that the No Loss of Suction claim applies only for the first ten ounces of dirt – about 25% of the bin volume in recent tests by IBR – and declines by up to one-third thereafter. As proven by the consumer survey conducted by Dr. Mazis, most consumers who read the disclaimer do not know how much of the vacuum bin will be filled by ten ounces of dust. (Attorney Decl., Ex. P. ¶25.) Many would not understand that the footnote disclaimer implies that the vacuum will lose suction after the 10 ounce mark. In this regard, the claim as used by Maytag is like the advertising at issue in Johnson & Johnson-Merck, where the defendant-advertiser claimed that its heartburn medication provided 24-hour relief, but failed to disclose clearly in the advertisement that the promised 24-hour relief did not begin until

five hours from the time the pill was ingested. Johnson & Johnson-Merck, 285 F. Supp. 2d at 390 (stating that the claim, "'One pill. 24 Hours. Zero Heartburn.' simply does not equal 'One pill. Wait 5 Hours. Only then Zero Heartburn for the next 24 hours.'") Similarly, Maytag's claim, "No Loss of Suction," simply does not equal "No Loss of Suction until only 25% of the bin is full. After that, big drop in suction."

Even if the footnote were of equal size and clarity to the main No Loss of Suction claim, it would still be false. The disclaimer itself refers explicitly to the ASTM F558 test, a modification of which Maytag purports to rely on to support its "No Loss of Suction" claim. Under the "establishment claim" doctrine, when a defendant explicitly purports to rely on the results of scientific tests or studies to establish the truth of its claim, a plaintiff can prove the falsity of that claim simply by showing that the tests relied on by the advertiser do not establish the proposition for which they were cited. See Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 62-63 (2d Cir. 1992); Accu-Sort Systems, Inc. v. Lazerdata Corp., 820 F.Supp. 928, 932 (E.D. Pa. 1998); BASF Corp. v. Old World Trading Co., 41 F.3d 1081, 1090-91 (7th Cir. 1994); Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997). As the NAD found in its decision, the modified ASTM F558 test relied on by Maytag does not establish the truth of Maytag's "No Loss of Suction" claim because the ASTM F558 as modified by Maytag does not adequately correlate with conditions of ordinary consumer use. (Attorney Decl., Ex. H at 34.)

Nor did the claim become true when modified by Maytag. (Attorney Decl., Ex. L.) Maytag added to the No Loss of Suction claim in two ways: by adding a statement in bold print immediately beneath the No Loss of Suction claim that "Vacuum Cleaner Suction Tests Do Not Represent Carpet Cleaning Ability" and by adding a sentence to the disclaimer stating that "[n]o

testing has established a correlation between suction performance and carpet cleaning ability in the home. Household results may vary." As the NAD found in responding to Dyson's compliance challenge, the proposed modification does nothing to further qualify or limit the scope of the broad No Loss of Suction claim, other than to confuse consumers by injecting tangential concepts that the claim is not related to carpet-cleaning ability.

Overall, as shown above, Dyson has carried its burden of showing the literal falsity of Maytag's claims. Nothing in the footnoted disclaimer cures the literal falsity, as proven by Dr. Mazis's consumer survey. The survey shows that the vast majority of consumers read only the headline No Loss of Suction claim. Few, if any, see, much less read, the tiny, footnoted disclaimer. Fewer still understand the disclaimer even when they read it.

Because there is persuasive evidence that the challenged advertisement is literally false, this Court should grant a preliminary injunction. See, e.g., W.L. Gore Assocs., Inc., 788 F. Supp. 800 (granting preliminary injunction where court was "convinced" that claim of "waterproofness" was false on its face); Upjohn Co., 641 F. Supp. 1209 (granting preliminary injunction where claim of "patented" and promotion of hair growth found to be literally false); Castrol Inc., 987 F.2d 939 (affirming grant of preliminary injunction where trial court found that defendant's claims of superiority for viscosity breakdown and engine protection were literally false); The Toro Co. v. Textron, Inc., 499 F. Supp. 241 (D. Del. 1980) (granting plaintiff injunctive relief where several claims by defendant regarding snow blowers found to be literally false); Novartis Consumer Health, Inc., 290 F.3d 578 (Affirming preliminary injunction where claim of "nighttime strength" antacid likely to be literally false).[13]

[13] The same operative facts also establish a likelihood of success on the merits of Dyson's claims under New York General Business Law §§ 349 and 350. Ciba, 348 F. Supp. 2d at 178, note 6; Princeton Graphics Operating, L.P., v. NEC Home Electronics (U.S.A.), Inc., 732 F. Supp. 1258,

2. Dyson Will Suffer Irreparable Harm If Maytag's False Packaging And Advertisements Continue.

Where, as here, an advertisement is false on its face, a plaintiff in the Third Circuit need not adduce evidence of consumer deception, because such deception is presumed. See Novartis Consumer Health, Inc., 290 F.3d at 586; Warner-Lambert Co., 204 F.3d at 92. Johnson & Johnson-Merck Consumer Pharms. Co., 19 F.3d at 129; Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 735 F. Supp. 597, 600 (D. Del. 1989).

In the Third Circuit, to be entitled to injunctive relief, a false advertising plaintiff need submit only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising. See, e.g., W.L. Gore Assocs., Inc., 788 F. Supp. at 810; Upjohn Co., 641 F. Supp. at 1224. "Irreparable injury does not require diversion of actual sales and it can include the loss of control of reputation, loss of trade, and loss of goodwill." Id. "[L]oss of market share constitutes irreparable harm." Novartis Consumer Health, Inc., 290 F.3d at 596 ("In a competitive industry where consumers are brand-loyal, . . . loss of market share is a 'potential harm which cannot be redressed by a legal or equitable remedy following a trial.'").

Dyson need not come forward with specific evidence that Maytag's ads have actually resulted in identifiable loss of sales to Dyson. Courts have long recognized the great difficulty of requiring such proof at the preliminary injunction stage in false advertising matters. For this reason, numerous courts have held that a showing of the mere likelihood of competitive injury, rather than concrete proof of actual sales diversion, is sufficient to warrant a § 43(a) injunction. Parkway Baking Co. v. Friehofer Baking Co., 255 F.2d 641 (3d Cir. 1958); Johnson & Johnson v. Carter-Wallace, Inc., 631 F.2d 186, 191 (2d Cir. 1980); Quabaug Rubber Co., v. Fabiano Shoe

1266 (S.D.N.Y. 1990); SQP, Inc. v. Sirrom Sales, Inc., 130 F. Supp. 2d 364, 366 (N.D.N.Y. 2001).

Co., Inc., 567 F.2d 154 (1st Cir. 1977); Ames Publ'g Co. v. Walker-Davis Publ'ns, Inc., 372 F.Supp. 1 (E.D. Pa. 1974). Here, of course, as cited above, Maytag / Hoover has admitted that it has made approximately $10 million in sales of the products with the offending ads – and that is just in the time since the injunction motion first was filed.

In a case directly analogous to this one, this Court has held that plaintiff had satisfied the irreparable injury standard. In W.L. Gore Assocs., Inc. v. Totes Inc., 788 F. Supp. 800 (D. Del. 1992), the plaintiff, much like Dyson, was "a pioneer and innovator" in its market and had "spent substantial resources in building its reputation as a leader in the field." Id. at 810. As such, the Court agreed that plaintiff's higher price was "directly related to the technological characteristics of the product." Id. Again, the same is true for Dyson's machines which offer Dyson's patented cyclonic technology at a premium price point. The defendant in W.L. Gore also advertised its product as "having the same technological characteristics, at a much lower price," much as Maytag has advertised that the Legacy and Fusion offer the same technological characteristics as the Dyson machines, but at a much lower price. Id. Moreover, just as Consumer Reports and other testing has found that the Legacy and Fusion do not offer the performance advertised by Maytag, the court found it unlikely that defendant's product in W.L. Gore possessed the characteristics advertised. Id. at 810-11.

Thus, in W.L. Gore, the Court held that there was a reasonable basis to believe that the plaintiff was likely to be damaged. Id. The Court reasoned that "[r]epeated claims of competitive superiority made to the same market of consumers will eventually lead to lost sales and deprive [plaintiff] of a legitimate competitive advantage." Id. Finally, the Court held that although "the scope and amount of this damage may be difficult to measure, it is sufficient for the grant of injunctive relief under § 43(a)." Id. There is no reason for this Court to treat

Dyson's case any differently.

Maytag's continued use of the No Loss of Suction claim, if not enjoined, is highly likely to cause severe and irreparable injury to Dyson for at least the following reasons. First, Maytag and Dyson are head-to-head competitors and market leaders in the upright vacuum cleaner market. Together, the two companies have a 40.5 % share of the market for household vacuum cleaners. (Attorney Decl., Ex. X ¶9.) A loss in sales occasioned by false advertising of one is highly likely to result in at least some gain by the other. (Attorney Decl., Ex. X ¶¶13-18.)

Second, the very nature of Maytag's advertising claim suggests the high potential for irreparable injury to Dyson. The "No Loss of Suction" claim has historically been identified with Dyson since the brand's first launch in the United States. (Id.) There can be little doubt that Maytag has commenced using precisely the same claim -- albeit falsely -- in predatory fashion to undermine Dyson's uniqueness in the market and to take sales from Dyson for its own benefit. Maytag's false No Loss of Suction claim, phrased almost identically to the Dyson claim, will likely result in actual and imminent loss to Dyson of not only sales but goodwill and market share losses that cannot be precisely quantified or repaired at a later date.

Maytag's false No Loss of Suction claim is analogous to a Lanham Act trademark infringement. Although Maytag does not expressly identify Dyson or overtly compare Maytag's vacuums to Dyson's vacuums, Maytag adopted the "No Loss of Suction" claim specifically because it has historically been identified with Dyson. Thus, Maytag's false advertising is designed to detract from the value of Dyson's truthful no loss of suction claim, and confuse the consumer into thinking that Maytag's vacuum performs as well as Dyson's. This reduces the consumer's incentive to select Dyson rather than Maytag and detracts from the value of Dyson's no loss of suction claims. See McNeilab, Inc. v. American Home Prod. Corp., 848 F.2d 34, 38

(2d Cir. 1988); see also U-Haul Int'l, Inc. v. Jartran, Inc., 793 F.2d 1034, 1041 (9th Cir. 1986) ("It is not easy to establish actual consumer deception through direct evidence. The expenditure by a competitor of substantial funds in an effort to deceive consumers and influence purchasing decisions justifies the existence of a presumption that consumers are, in fact, being deceived").

Finally, Maytag's own Vice President of Marketing has actually admitted that Maytag will continue to use the claim in advertising in order to "hit Dyson where they claim their superiority." (Attorney Decl., Ex. K.) He has further said that Maytag will continue to use the claim, even though it does not "believe in" No Loss of Suction. (Id.) This constitutes strong evidence of Maytag's intent to cause sales loss specifically to Dyson, as opposed to competitors more generally.

C. The Equities Weigh Decidedly in Favor of Injunctive Relief.

The balance of equities falls squarely in Dyson's favor because, by engaging in false, deceptive, and misleading advertisements, Maytag is engaging in illegal and wrongful conduct to the detriment of Dyson and the general consuming public as a whole. "[T]he injury a defendant might suffer if an injunction were imposed may be discounted by the fact that the defendant brought that injury upon itself." Novartis Consumer Health, Inc., 290 F.3d at 596. Maytag has no cognizable rights in the dissemination of deceptive falsehoods. See Zeneca Inc. v. Eli Lilly and Co., C.A. No. 99-1452 (JGK), 1999 WL 509471 at *41 (S.D.N.Y. 1999) (false advertising defendant "can assert no equitable interest in the perpetuation of an advertising campaign that is literally false") (citation omitted). Indeed, Maytag has stated that it "does not believe in" the "No Loss of Suction" claim but is continuing to use it as a way to "hit Dyson," thus giving lie to improper motivations for continuing to use the claim in advertising.

D. The Public Interest Strongly Favors Injunctive Relief.

"There is a strong public interest in the prevention of misleading advertisements. . . ." Novartis Consumer Health, Inc., 290 F.3d at 597. "The public has a right not to be deceived or confused." W.L. Gore Assocs., Inc., 788 F. Supp. at 813; see also Upjohn Co., 641 F. Supp. at 1225-26 ("Customer confusion is by its very nature against the public interest."). "The public has a right to information that will allow them to assess the quality of a product and to accurately price the product in accordance with their priorities and desires." W.L. Gore Assocs., Inc., 788 F. Supp. at 813. Maytag's advertising "deprives the consumer of this information and deceives them into thinking that they are buying a less expensive equivalent, a bargain on a quality product." Id.

Furthermore, issuing an injunction here would reinforce the important public policies served by the NAD's self-regulatory forum. Maytag has blatantly ignored the NAD's recommendation – made both in April and August of 2006 – that Maytag discontinue its "No Loss of Suction" claim, even after Maytag indicated in a written statement that it would abide by the NAD's decision.

In the face of Maytag's duplicitous behavior, Dyson is left with no choice but to seek emergency judicial intervention in order to vindicate its rights. Granting the relief requested by Dyson will advance the interests that the federal and state false advertising statutes specifically were designed to protect.

E. The Relief Requested Is Appropriate And Necessary.

Among other preliminary remedies that Dyson requests be entered, Dyson respectfully requests that Maytag be required to affix stickers to Fusion and Legacy product packages in the marketplace and chain of distribution to cover over the false No Loss of Suction claim. Where

the vacuums themselves are displayed outside of the cartons at point of purchase, Dyson requests that the No Loss of Suction claim on the units be covered with a sticker as well. There is ample precedent for an order requiring such relief at the preliminary injunction stage. See Grondin v. Rossington, 690 F.Supp. 200, 211 (S.D.N.Y. 1988); Ladas v. Potpourri Press, 846 F.Supp. 221, 224 (E.D.N.Y. 1994); Creative Technology v. SRT, Inc., 1993 WL 603292 at *3 (N.D. Cal. 1993).

V. CONCLUSION

For the foregoing reasons, the Court should grant the relief sought by Dyson in this motion for a preliminary injunction and Maytag should immediately be required to 1) sticker or otherwise remove the No Loss of Suction claim, or any words of substantially similar meaning or import, from any future shipment of Hoover Fusion or Maytag Legacy vacuums, including the planned April 2007 shipment described in Maytag's Special Interrogatory Responses; 2) take commercially reasonable steps to ensure that the No Loss of Suction claim for the Hoover Fusion and Maytag Legacy upright residential vacuum cleaners is removed from all displays, including in-store displays, advertisements of any kind and websites, including retail and re-sale websites; and 3) cease stating or communicating, directly or indirectly, by words or visual images, in any advertising, packaging, promotional materials or promotional activities for the Hoover Fusion or

Maytag Legacy upright residential vacuum cleaners that the vacuums provide "No Loss of Suction" or words of substantially similar meaning or import.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

C. Barr Flinn (No. 4092)
John W. Shaw (No. 3362)
Chad S.C. Stover (No. 4919)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
cstover@ycst.com

OF COUNSEL:

Chad S. Hummel
Kathrin A. Wanner
MANATT, PHELPS & PHILLIPS, LLP
7 Times Square
New York, New York 10036
(212) 790-4500

Attorneys for Plaintiff Dyson, Inc.

Dated: April 18, 2007

CERTIFICATE OF SERVICE

I, Chad S.C. Stover, hereby certify that on April 18, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Francis DiGiovanni, Esquire
James D. Heisman, Esquire
CONNOLLY BOVE LODGE & HUTZ LLP
The Nemours Building – 8th Floor
1007 N. Orange Street
Wilmington, Delaware 19801

I further certify that on April 12, 2007, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following in the manner indicated:

BY E-MAIL

Ray L. Weber, Esquire
RENNER, KENNER, GREIVE, BOBAK,
TAYLOR & WEBER
400 First National Tower
Akron, OH 44308

Kimball R. Anderson, Esquire
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601-9703

YOUNG CONAWAY STARGATT & TAYLOR, LLP

C. Barr Flinn (No. 4092)
John W. Shaw (No. 3362)
Adam W. Poff (No. 3990)
Chad S.C. Stover (No. 4919)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
cstover@ycst.com
Attorneys for Dyson Technology Limited and Dyson, Inc.

TAB 1

Westlaw.

Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 1999 WL 509471 (S.D.N.Y.), 1999-2 Trade Cases P 72,603
(Cite as: Not Reported in F.Supp.2d)

Zeneca Inc. v. Eli Lilly and Co.
S.D.N.Y.,1999.

United States District Court, S.D. New York.
ZENECA INC., Plaintiff, and
BARR LABORATORIES, INC., Plaintiff-Intervenor,
v.
ELI LILLY AND COMPANY, Defendant.
No. 99 CIV. 1452(JGK).

July 19, 1999.

Harold P. Weinberger, Esq., Kramer Levin Naftalis & Frankel LLP, New York, for the Plaintiff.
Michael K. Atkinson, Esq., Winston & Strawn, Washington, D.C., Daniel Murdock, Esq., Winston & Strawn, New York, for the Plaintiff Intervenor.
Nina M. Gussack, Esq., Pepper Hamilton LLP, Philadelphia, PA, for the Defendant.

OPINION AND ORDER

KOELTL, District J.

***1** The plaintiff, Zeneca Inc. ("Zeneca") [FN1], and plaintiff-intervenor Barr Laboratories, Inc. ("Barr"), have sued the defendant, Eli Lilly and Company ("Eli Lilly"), under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and under the common law and statutory law of New York that prohibits unfair competition and deceptive trade practices. Zeneca is the manufacturer of the breast cancer drug tamoxifen citrate (hereinafter "tamoxifen citrate" or "tamoxifen"), which Zeneca markets and sells under the name Nolvadex. Barr distributes generic tamoxifen citrate pursuant to a licensing agreement with Zeneca. Tamoxifen citrate has been approved by the Food and Drug Administration ("FDA") for the reduction of the incidence of breast cancer in women at high risk of developing the disease.

FN1. Since this action was filed, Zeneca Inc. has merged with a pharmaceutical company called Astra. The merged entity is now called AstraZeneca Inc. Tr. at 2.

Eli Lilly manufactures and sells the drug raloxifene hydrochloride (hereinafter "raloxifene") under the name Evista. Evista has been approved by the FDA for the prevention of osteoporosis in postmenopausal women. Zeneca and Barr allege that Eli Lilly is making three false claims about Evista: 1) that Evista has been proven to reduce the risk of breast cancer, 2) that Evista is comparable or superior to tamoxifen citrate for the prevention of breast cancer, and 3) that Evista has been indicated or approved by the FDA for the prevention of breast cancer. Defendant Eli Lilly argues that it has not made the second or third claims alleged. As to the first claim, the defendant argues that such a claim is not false because Evista has been proven to reduce the risk of breast cancer.

Zeneca and Barr have moved for a preliminary injunction. Following extensive expedited discovery, the Court held a five-day evidentiary hearing. As explained in detail below in the Court's Findings of Fact and Conclusions of Law, Eli Lilly has been promoting Evista with the claim that it has been established that it reduces the risk of breast cancer. That claim is based on the results of a significant clinical trial-the Multiple Outcomes of Raloxifene Evaluation ("MORE") study-but the results of that trial do not prove that it has been established or proven that Evista reduces the risk of breast cancer. Further research is necessary to support the claim, and the FDA has specifically required Eli Lilly to include in the label for Evista, while discussing the results of the MORE trial, that "[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established." Def.'s Exh. H (Evista Package Insert Revised as of Dec. 2, 1998) at 8. Hence, it is literally false for Eli Lilly to promote Evista with the claim that it has been established or proven that Evista reduces the risk of breast cancer. It is important in the public interest that the results of the MORE trial, as discussed below, be disseminated so that doctors and public health professionals can assess and understand the results of that study. It is also important, however, that the results of that study be truthfully disseminated and that false claims not be made, because false claims will not only hurt competitors who are marketing a drug that has been established to reduce the risk of breast cancer, but such false claims will also harm the public interest in assuring that truthful information about highly significant drugs is disseminated.

***2** As a preliminary matter, during the evidentiary hearing the parties raised a number of hearsay objections. The Court received the evidence, including hearsay evidence such as affidavits, subject

to a motion to strike. In reaching the Findings of Fact and Conclusions of Law, the Court has considered the hearsay objections raised by all parties. The Court has concluded that the objections do not warrant exclusion of the evidence. The Court has, however, carefully considered the reliability of all the disputed evidence and will separately discuss the evidence as to which objections were made. The strict rules of evidence do not apply to a hearing on a motion for a preliminary injunction. *See, e.g.,* Securities and Exch. Comm'n v. Cherif, 933 F.2d 403, 412 n.8 (7th Cir.1991), *cert. denied,* 502 U.S. 1071 (1992); *Asseo v. Pan American Grain Co.,* 805 F.2d 23, 25-26 (1st Cir.1986); *Commodity Futures Trading Comm'n v. American Metal Exch. Corp.,* 693 F.Supp. 168, 173 (D.N.J.1988); *Delman Fabrics Inc. v. Holland Fabrics, Inc.,* 84 Civ. 2512, 1984 WL 367, at *5 (S.D.N.Y. May 17, 1984). The Court has, nevertheless, applied the Federal Rules of Evidence in determining the weight to be accorded the evidence that was introduced and has also assessed whether the evidence would be admissible under the Federal Rules of Evidence.

The defendant objects first to the admissibility of the "call notes" that were written by Eli Lilly sales representatives about their meetings with and "detailing" of doctors concerning Evista. The defendant argues that the call notes are inadmissible hearsay and do not meet any of the exceptions to the hearsay rule.

As an initial matter, as noted above, the Court may consider hearsay evidence in a preliminary injunction hearing. In any event, the call notes satisfy the business records exception to the hearsay rule. *See* Fed.R.Evid. 803(6). The testimony of Newt Crenshaw, Eli Lilly's Vice President of U.S. Sales, established that sales representatives are required to submit call notes in the course of their duties, that they are trained in how to make call notes, and that the call notes are required to be typed up as soon as possible after each visit with a doctor-usually the same day as the visit itself. Moreover, the call notes are intended to be accurate because sales representatives rely on the call notes when planning future meetings with doctors. The call notes are also backed up on a central computer system. Tr. at 152-63 (Crenshaw); *see also* Tr. at 852-53, 875-78 (Torres) (indicating that call notes are like a "diary" and that they are used by sales representatives and their partners to record accurate information). It is plain that the notes are made at or near the time of the meeting with the doctors by a sales representative with knowledge of the meeting, that the call notes are kept in the ordinary course of Eli Lilly's business, and that it was the regular practice of Eli Lilly's sales representatives to write and keep call notes. Thus the call notes are admissible under Rule 803(6). *See, e.g., United States v. Goodchild,* 25 F.3d 55, 62 (1st Cir.1994).

***3** The call notes are also admissible as admissions under Federal Rule of Evidence 801(d)(2)(D). To be admitted under Rule 801(d)(2)(D), a party must demonstrate only "(1) the existence of the agency relationship, (2) that the statement was made during the course of the relationship, and (3) that it relates to a matter within the scope of the agency." *Pappas v. Middle Earth Condominium Assoc.,* 963 F.2d 534, 537 (2d Cir.1992). In this case, the plaintiff has demonstrated that an agency relationship existed between the sales representatives and Eli Lilly, that the statements in the call notes were made during the course of that relationship, and that the call notes concerned a matter within the scope of the agency relationship-namely the promotion and detailing of Evista. Thus the call notes are admissible under Rule 801(d)(2)(D).

Moreover, the probative value of the notes is not outweighed by any danger of unfair prejudice. The notes are highly probative of what the representatives said, which is an important issue in the case, they are not inflammatory, and they do not present a situation where the Court is being asked to consider them for an improper purpose. There is no basis for arguing they should be excluded under Federal Rule of Evidence 403.

The defendant next moves to exclude certain FDA documents on hearsay grounds. But hearsay evidence is admissible in a hearing on a preliminary injunction. Further, the documents are not hearsay to the extent that they are not offered for their truth. Here, the plaintiff seeks to admit the FDA documents for the fact of what the FDA said to Eli Lilly about Evista, the results of the MORE study, and the meaning of the language in the Evista label. The documents are relevant to Eli Lilly's contention concerning the FDA's interpretation of the MORE study and the meaning of the language on Evista's label stating that "[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established." Thus the documents are admissible as non-hearsay.

The FDA documents-in particular the minutes of the January 1999 and May 1999 meetings-are also admissible under the exception to the hearsay rule for public records that set forth "factual findings

resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness." Fed.R.Evid. 803(8)(c). The Meeting Minutes sought to be admitted contain factual findings by the FDA concerning Evista's efficacy for breast cancer prevention. The Minutes were the result of a timely review. There is no dispute that the FDA has the authority to and routinely does evaluate clinical data submitted by pharmaceutical companies and that the FDA's Division of Oncology Drug Products specifically performs this function with respect to cancer drugs. Tr. at 428-29 (Carlson); Tr. at 740-41 (Cummings). Moreover, the FDA's investigators have technical skill and expertise and were unbiased. In addition, other factors confirm the reliability of the documents. For example, Eli Lilly was given the opportunity to review the Meeting Minutes and to correct any errors in them. Tr. at 1117-18 (Dere); Def.'s Exh. K-9 (stating in cover letter to Meeting Minutes from May 11, 1999 that "[t]hese minutes are the official minutes of the meeting. You are responsible for notifying us of any significant differences in understanding you have regarding the meeting outcomes"). Thus the FDA documents, including the Meeting Minutes, are trustworthy and admissible.

***4** The fact that the Minutes are the FDA's non-final factual findings does not render the reports untrustworthy and inadmissible. *See* *Reynolds v. Giuliani*, 98 Civ. 8877, 1999 WL 33027, at *2 (S.D.N.Y. Jan. 21, 1999); *Meriwether v. Coughlin*, 879 F.2d 1037, 1039 (2d Cir.1989) (noting admission of a page of an interim report). The *Pullman* case cited by the defendant is not to the contrary because it affirmed the exclusion of a non-final report by a government agency not merely because the report was an "interim" report but also because the report, unlike the FDA minutes, "expressly declined to state a conclusion on the most significant safety question" at issue in that case. *See* *City of New York v. Pullman Inc.*, 662 F.2d 910, 914-15 (2d Cir.1981). In sum, the defendant has not demonstrated that the FDA Meeting Minutes are untrustworthy and thus the motion to exclude them is denied. The defendant was, of course, permitted to introduce evidence that goes to the weight to be given to the factual conclusions stated in the Meeting Minutes and that evidence has been considered by the Court.

Finally, the Court will consider the doctors' affidavits that have been submitted by the defendant. These affidavits attempt to contradict some of the call notes. Def.'s Exhs. T-4 through R-5. The strict rules of evidence do not apply in a preliminary injunction hearing. However, the Court is mindful of the fact that there is a preference for live testimony when the Court is called on to resolve disputed issues of fact. *See, e.g.*, *Davis v. New York City Housing Auth.*, 166 F.3d 432, 437-38 (2d Cir.1999) ("When a factual issue is disputed, oral testimony is preferable to affidavits."); *Fox Broadcasting Co. v. Fox Broadcasting Co.*, 86-4989, 1986 WL 11445, at *1 (E.D.Pa. Oct. 9, 1986) (determining that the Court would consider affidavits in deciding a motion for a preliminary injunction even though the authors of the affidavits were not available to be cross-examined, but noting that the Court would be aware of that objection "in determining the evidentiary weight of any relevant affidavit"); *cf.* *Securities and Exch. Comm'n v. Petrofunds, Inc.*, 414 F.Supp. 1191, 1196 (S.D.N.Y.1976) (noting that when district judges are asked to award preliminary relief, they are "not to resolve a factual dispute on affidavits or depositions for then (they are) merely showing a preference for one piece of paper to another") (internal citation omitted) (Weinfeld, J.). Thus although the Court will consider the doctors' affidavits, the affidavits are necessarily of less weight than the live testimony of witnesses who were available and subject to cross-examination at the hearing.

The Court now makes the following findings of fact and reaches the following conclusions of law.

I.

FINDINGS OF FACT

A. The Parties

1. Plaintiff Zeneca is a Delaware corporation with its principal place of business in Wilmington, Delaware. The company researches, develops, and produces medicines. (Compl. ¶ 6; Ans. ¶ 6.) Zeneca manufactures and sells a breast cancer drug called Nolvadex (tamoxifen citrate). Nolvadex has been approved by the FDA for the reduction of the incidence of breast cancer in women at high risk of developing the disease. Pl.'s Exh. 3 (Nolvadex label) at p. 13.

***5** 2. Defendant Eli Lilly is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Eli Lilly is a global pharmaceutical corporation that, like Zeneca, researches, develops, and markets medicines for use in a variety of

therapeutic areas. Eli Lilly advertises, distributes, and sells its pharmaceutical products throughout the United States. (Compl. ¶ 7; Ans. ¶ 7.)

3. Plaintiff-intervenor Barr is a New York corporation with its principal place of business in Pomona, New York. Pursuant to a Distribution and Supply Agreement between Barr and Zeneca, Barr purchases from Zeneca and then distributes generic tamoxifen citrate under its own name. Tamoxifen citrate accounts for over 60% of Barr's net sales. Barr also markets two hormone replacement drugs for use in the treatment of osteoporosis, which compete directly with Eli Lilly's osteoporosis drug Evista. (Barr Compl. ¶ 8; Tr. at 548, 552-53 (Sawyer)).[FN2]

FN2. Barr moved to intervene approximately one month after Zeneca commenced this action. On May 4, 1999, the Court granted Barr's motion pursuant to Federal Rule of Civil Procedure 24(a)(2) and (b)(2). *See* Order dated May 4, 1999. Barr did not participate in expedited discovery but did attend and offer testimony at the hearing on the preliminary injunction.

B. Zeneca's breast cancer drug Nolvadex

4. In the 1970s, scientists at Zeneca developed a synthetic hormone "antagonist" called tamoxifen citrate, which was shown to have significant "anti-estrogenic" properties. Tamoxifen "antagonizes," or counteracts or neutralizes, the cancer-promoting effects of estrogen in the breast by binding itself to the estrogen receptor in a cancerous cell. The presence of an anti-estrogen such as tamoxifen prevents estrogen from binding to the receptor, which in turn affects tumor growth. Tamoxifen has since been used, either in addition to or in lieu of more drastic and invasive forms of therapy, to treat both early and advanced-stage breast cancer and to prevent recurrence. Since it was first discovered nearly thirty years ago, tamoxifen has become the most widely prescribed treatment for breast cancer. Tr. at 42, 46-47 (Anson); Tr. at 299-301 (Lewis).

5. Zeneca markets tamoxifen under the brand name Nolvadex. Nolvadex is one of Zeneca's most successful and widely-prescribed products. Nolvadex was originally approved by the FDA for the treatment of advanced breast cancer in 1978. It was later approved for other uses, including early stage adjuvant treatment, this is, treatment after the primary treatment for breast cancer, such as surgery. Tr. at 42, 47 (Anson); Tr. at 299-302 (Lewis).

6. Beginning in 1992, the National Cancer Institute (NCI) sponsored a clinical trial, conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP), to determine whether the use of tamoxifen could play a role in reducing the incidence of breast cancer in healthy women at high risk of developing the disease. This Breast Cancer Prevention Trial ("BCPT") enrolled more than 13,000 pre- and post-menopausal women at 131 different clinical sites. Tr. at 49 (Anson); Tr. at 306-08 (Lewis); Tr. at 440 (Carlson).

7. All the women recruited for the study were determined to be at high risk for developing breast cancer. Each woman qualifying for the study had to satisfy at least one of the following three enrollment criteria: (i) a history of lobular carcinoma in situ-benign breast tumors which are a known precursor to invasive or metastatic breast cancer, (ii) a score of 1.67 or higher on a breast cancer risk assessment model called the GAIL model, [FN3] and/or (iii) an age of 60 or older. Thirty percent of the patient population in the BCPT qualified based on the age criteria alone. The remainder fell into the other two risk categories. Tr. at 306-10 (Lewis).

FN3. The GAIL risk assessment model is a mathematical formula used to predict a woman's chances of developing breast cancer based on all known risk factors, including age, family history of breast cancer, age at onset of menstruation, age at first live birth, and number of benign breast biopsies. Tr. at 298-99 (Lewis); Tr. at 417 (Carlson).

*6 8. The BCPT study demonstrated that the ongoing use of tamoxifen citrate by women at high risk of developing breast cancer reduced the incidence of invasive breast cancer by 49 percent. The results were so positive that NCI discontinued the study in March of 1998 to allow all high-risk women-including those in the placebo arm of the study-to benefit from its findings. Tr. at 49-50 (Anson); Tr. at 310-12 (Lewis).

9. In April 1998 Zeneca submitted a supplemental New Drug Application ("sDNA") to the FDA seeking approval of tamoxifen for use in reducing the incidence of breast cancer. Based upon the results of the Breast Cancer Prevention Trial, on October 29, 1998 the FDA, after an expedited review, approved tamoxifen for the reduction of the incidence of breast cancer in both pre- and postmenopausal women at high risk of developing the disease. Tr. at 47-49

(Anson); Tr. at 314-15 (Lewis); Pl.'s Exh. 3 (Nolvadex Label) at p. 13.

10. In the period between the conclusion of the BCPT trial and the FDA's approval of tamoxifen for the reduction of the risk of breast cancer, Zeneca devoted substantial time, energy, and resources to developing a marketing plan for tamoxifen's new indication. According to Lisa Anson, Zeneca's Business Development Manager for Oncology, the new indication for tamoxifen was viewed as a "very significant opportunity" for Zeneca-a potential "blockbuster drug." Tr. at 51-52 (Anson). Ms. Anson also highlighted the difficulties facing Zeneca in marketing tamoxifen for breast cancer risk reduction because of the fact that "nobody has ever had a drug in the area of prevention" and "there [was] no ... market for risk reduction or prevention." Tr. at 52 (Anson). Zeneca thus had to create the market from scratch. Tr. at 51-53, 100 (Anson).

11. Shortly after FDA approval, in early November 1998 Zeneca began promoting tamoxifen for its new indication for the reduction of the risk of breast cancer. Tr. at 53 (Anson).

12. Over time, researchers have discovered that Nolvadex is associated with an increase in the risk of uterine cancer. This increased risk was not discovered until about ten years after tamoxifen was approved in the United States. Tr. at 303-05, 364 (Lewis).

C. Eli Lilly's osteoporosis drug Evista

13. One of Eli Lilly's products in the field of women's health is an osteoporosis drug called Evista. Evista, which contains the active ingredient raloxifene hydrochloride, was first approved by the FDA in December 1997, solely for the prevention of osteoporosis in postmenopausal women. Tr. at 54 (Anson); Tr. at 317 (Lewis).

14. Evista is an important product for Eli Lilly. At least during the period right after launch, however, sales of Evista were disappointing. Tr. at 855 (Torres). Eli Lilly has since revised its Evista sales projections downward. Tr. at 856-57 (Torres).

15. While breast cancer is often associated with a high cumulative exposure to estrogen, osteoporosis afflicts women at the opposite end of the hormonal spectrum-those with reduced levels of estrogen. Estrogen acts on the bone to maintain bone density and thereby prevent osteoporosis. This may explain why postmenopausal women, who have less circulating estrogen, become increasingly vulnerable to osteoporosis. Tr. at 720 (Cummings); Tr. at 337-38 (Lewis); Tr. at 456-57 (Carlson).

*7 16. Raloxifene, like tamoxifen, has been shown to have both estrogenic and anti-estrogenic properties. Tr. at 317-18 (Lewis). However, raloxifene is structurally different from tamoxifen. Tr. at 317-19 (Lewis).

17. In the mid-1990s, Eli Lilly scientists began a series of ten osteoporosis studies, one of which was titled "Multiple Outcomes of Raloxifene Evaluation" or "MORE." There is no dispute that the results from nine of these studies, even when combined, did not demonstrate that raloxifene decreases the incidence of newly diagnosed breast cancer. Tr. at 655 (Cummings); Tr. at 905-06 (Eckert); Tr. at 1125 (Dere); Lippman Dep. Tr. at 155-56.

18. The MORE study itself was a randomized, double-blind, placebo-controlled, multicenter clinical trial. The women in the study were randomly assigned to be given either raloxifene or a placebo, and neither they nor their doctors knew whether they were taking raloxifene or a placebo. Tr. at 608-09, 622 (Cummings); Pl.'s Ex. 37 (Clinical Study Main Report for the MORE study) at EV 2718 1545. The MORE study was designed to examine the outcomes of exposure to raloxifene and to gather the data necessary to secure an indication for Evista for the prevention of postmenopausal osteoporosis. Tr. at 618-19 (Cummings).

19. As discussed below, Eli Lilly has predicated its claim that Evista has been proven to reduce the incidence of breast cancer on the results of the MORE study. As of the date the study was terminated in early 1999, a total of forty cases of invasive breast cancer were reported among MORE study participants, 27 for the patients taking placebo and 13 for the nearly twice as many patients taking raloxifene. Tr. at 406-10 (Carlson); Def.'s Exh. L-9 ("The Effect of Raloxifene on Risk of Breast Cancer in Postmenopausal Women," *The Journal of the American Medical Association ("JAMA")*, June 16, 1999) [FN4] at 2192. The results of the MORE study are discussed in greater detail below. Eli Lilly also plans to participate in a five-year comparative trial titled Study of Tamoxifen and Raloxifene ("STAR"), sponsored by NCI/NSABP, which will test the potential efficacy of Evista against the proven efficacy of tamoxifen in reducing the risk of breast cancer in postmenopausal women. Enrollment in STAR has just begun and the study likely will not be completed for at least five years. Tr. at 322 (Lewis); Pl.'s Exh. 34 (NSABP Protocol P-2 Study of Tamoxifen and Raloxifene (STAR) for the Prevention of Breast Cancer) at Z 15096.

FN4. The Journal of the American Medical Association, or "JAMA," is a prestigious medical journal in the United States. Lippman Dep. Tr. at 45.

D. Eli Lilly's promotional claims for Evista

20. Although Evista is an osteoporosis drug, Eli Lilly planned to market Evista for breast cancer prevention. Eli Lilly's market strategy documents and business plans contain numerous references to Evista's long-term "value proposition" and brand strategy that "Evista is the only single agent proven to safely protect women after menopause against three of the most serious threats to their health and independence: osteoporosis, breast cancer, and cardiovascular disease." Pl.'s Exh. 9 at EV 2014-1599; Pl.'s Exhs. 11 & 67. Eli Lilly witnesses have also described Evista's "competitive advantage," at least over the long term, as protecting against the risk of breast cancer. Tr. at 217-19 (Torres).

***8** 21. Eli Lilly's internal documents also reflect the company's understanding, based on market research it commissioned, that if Eli Lilly could make a breast cancer prevention claim for Evista, it would have a substantial impact on physicians and differentiate Evista from competitors. Tr. at 217-24 (Torres); Pl.'s Exh. 9 at EV 2014-1582, 1585, 1602.

22. A primary form of advertising for Evista takes place through in-person visits by Eli Lilly sales representatives to physicians. Tr. at 144 (Crenshaw); Tr. at 245-47 (Nicholson); Tr. at 857-59 (Torres). Sales representatives are an important source of information for physicians about prescription drugs, and physicians-who are the "gatekeepers" for patients, Tr. at 233-34 (Harenberg)-often rely to some extent on the information they are given by sales representatives in determining what drugs to prescribe. It is thus critical that sales representatives convey accurate and reliable information when detailing drugs to physicians. Tr. at 44-45 (Anson); Tr. at 166-68 (Crenshaw).

23. Eli Lilly has approximately one thousand primary case sales representatives. These representatives receive a base salary as well as a bonus based on the number of prescriptions for Eli Lilly drugs written by physicians they visit. The representatives detail an average of eight doctors per day, which translates into nearly 200 detail visits each month. Tr. at 147-49, 151 (Crenshaw); Tr. at 857 (Torres). The evidence suggests that each detail visit lasts an average of just two to three minutes. During those two to three minutes, representatives must detail several Eli Lilly drugs, not just Evista. Tr. at 798-99 (Torres).

24. Eli Lilly has several measures in place to ensure that its representatives convey authorized and intended messages to physicians and that they follow-up appropriately in subsequent visits. To that end, Eli Lilly provides its sales representatives with selling scripts or "verbatims" that tell them what to say to doctors about Evista either proactively or in response to questions from physicians. Tr. at 801-02 (Torres).

25. In addition, Eli Lilly representatives are trained and required to maintain written notes, prepared as soon as possible after each visit with a physician, encapsulating the visit. The purpose of these "call notes" is to provide an accurate record of what the sales representative and the doctor discussed and to record contemporaneously what the representative believes were the most salient aspects of each visit. Eli Lilly's Vice President of U.S. Sales, Newt Crenshaw, testified that the call notes are "utilized by that sales representative and/or their partner in the ongoing dialogue or promotional efforts with a given physician." Tr. at 154 (Crenshaw); *see also* Tr. at 152-60 (Crenshaw); Tr. at 877-78 (Torres). As contemporaneous written accounts, they are the best evidence of what the representatives communicated to doctors during their detail visits.

***9** 26. Eli Lilly also relies on market research to track the messages that its sales representatives are conveying to physicians. Tr. at 168 (Crenshaw). In the case of Evista, Eli Lilly commissioned a series of surveys conducted bimonthly throughout 1998 by a market research firm called Richard Day Research. Under Eli Lilly's guidance and direction, Richard Day periodically surveyed hundreds of physicians who had recently been detailed by an Evista sales representative and asked them among other things to describe the message the Eli Lilly representative had communicated about Evista. Tr. at 234-36 (Harenberg). According to John Ross, the Project Manager at Richard Day who together with Eli Lilly designed and conducted this survey, "one of the goals of the study [was] to get a sense of the message that was being delivered to those doctors from those reps and see if specific messages were being recalled by those doctors or not." Tr. at 519 (Ross).

27. The evidence adduced at the hearing demonstrates that since at least October 1998, Eli Lilly representatives have been communicating to physicians that Evista has been proven to reduce the risk of breast cancer and that Evista is comparable or superior to tamoxifen in reducing the risk of breast cancer. This evidence includes the following: (i) Eli Lilly's detail scripts distributed to sales representatives in November and December 1998, (ii) the sales representatives' call notes, (iii) the testimony

of Eli Lilly business executives, (iv) eyewitness testimony, and (v) a Richard Day survey conducted in late November and early December 1998.

28. In mid-1998, even before tamoxifen had received an indication from the FDA for breast cancer risk reduction, Zeneca began receiving anecdotal reports that Eli Lilly was promoting Evista for breast cancer prevention. In late May 1998, Zeneca's Chief Executive Officer wrote to Eli Lilly's president asking him to put a halt to any improper breast cancer promotion by the company's sales representatives. *See* Pl.'s Exh. 1 (Ltr. from T.F.W. McKillop to Sidney Taurel dated May 29, 1998). In June 1998, Eli Lilly's president denied Zeneca's accusations and communicated to Zeneca that any such claims by Eli Lilly sales representatives would be cause for "serious disciplinary action" by the company. His letter assured Zeneca that

sales representatives have been instructed repeatedly and in no uncertain terms that they cannot promote Evista for the prevention of breast cancer. We regularly check promotional message recall with our customers through controlled market research, and breast cancer prevention has not been mentioned, as you would expect were our representatives promoting Evista for that use.

Pl.'s Exh. 2 (Ltr. from Sidney Taurel to T.F.W. McKillop dated June 3, 1998); Tr. at 54-59 (Anson).

29. Zeneca was reassured by the letter from Eli Lilly's president, concluding that Eli Lilly "took our issues very seriously" and responded "as you would expect them to behave as a major pharmaceutical company." Tr. at 59 (Anson). However, in late 1998, after the launch of the new indication for breast cancer prevention for Nolvadex, Zeneca gradually began to hear more and qualitatively broader anecdotal evidence that Eli Lilly representatives were making the claims in question. Zeneca also commissioned market research as part of its Nolvadex launch, and that research, particularly the studies completed in January 1999, provided more concrete proof that Eli Lilly's representatives were making breast cancer risk reduction claims. Tr. at 62-68 (Anson).

***10** 30. As set forth below, it appears that Eli Lilly began communicating two of the claims in question-that Evista has been proven to reduce the risk of breast cancer and that Evista is comparable or superior to tamoxifen in reducing the risk of breast cancer-in a systematic way in late 1998, when Eli Lilly issued new verbatim scripts for its sales representatives. However, there is insufficient evidence to conclude that Eli Lilly was communicating the third alleged claim-that Evista is approved or indicated by the FDA for reduction of the risk of breast cancer.

1. *The November and December 1998 detailing scripts*

31. Until November 1998, Eli Lilly had in place a verbatim script which stated only that recent data have shown that Evista "may also prevent breast cancer." Pl.'s Exh. 14 (Document re: Sales Representative Verbatim Response to Evista and Breast Cancer Prevention Questions dated May 14, 1998). This was part of a verbatim response that could be given to an unsolicited question by a doctor as to whether Evista prevented breast cancer. It was linked to the message that Evista prevented osteoporosis without increasing the risk of breast cancer. Shortly after Zeneca obtained the risk reduction indication for tamoxifen from the FDA, Eli Lilly revised its selling script for its sales representatives. Tr. at 867 (Torres); Pl.'s Exh. 15 (Document re: Questions comparing the ability of Evista and tamoxifen to prevent the incidence of newly diagnosed breast cancers dated Nov. 18, 1998). In an effort to position Evista as a drug that could also be used in the same way as tamoxifen, Eli Lilly told its representatives in November 1998 that in response to unsolicited questions from physicians concerning the comparative efficacy of the two drugs, Eli Lilly representatives should reply as follows:

Dr., Evista is not approved for the prevention of breast cancer. However, let me share with you these data we currently have with regard to Evista reducing the incidence of breast cancer.

Dr., these data come from about 13,000 women age 45-80 enrolled in our osteoporosis prevention and treatment studies. Women who have taken Evista for an average of 29 months had a greater than 50% reduction in the incidence of newly-diagnosed breast cancers compared with the placebo group. While we do not currently have head-to-head trials, *these results are similar to those for tamoxifen in women at high risk of breast cancer.*

Pl.'s Exh. 15 at EV 2609 327-28 (emphasis added). The script went on to promote the purported superior safety profile of Evista over tamoxifen: "Dr., a very distinct difference between Evista and tamoxifen lies in the uterine safety profile. In women, tamoxifen increases endometrial thickness, and increases the risk of polyps, and endometrial cancer. In contrast, Evista, does not increase endometrial thickness or increase the risk of endometrial cancer." *Id.* at 328.

32. As Eli Lilly has acknowledged, without a head to

head trial there is no scientific basis for drawing this comparison, particularly the statistical comparison of the efficacy of the two drugs in the same population. Tr. at 180 (Crenshaw); Tr. at 740 (Cummings). Indeed, Eli Lilly's Director of Oncology Business testified that he could think of no situation in which it would be appropriate for an Eli Lilly sales representative to compare tamoxifen to Evista. Tr. at 251 (Nicholson).

***11** 33. In December 1998, the FDA approved a change in the safety portion of Evista's label to include results of the MORE study with respect to breast cancer, which was a secondary endpoint of the MORE study. Tr. at 619 (Cummings); Tr. at 846 (Torres); Tr. at 914-16 (Eckert). The approved language in the new package insert stated that:

Among 7017 women randomized to raloxifene, there were 6 cases of invasive breast cancer per 14,605 person-years of follow-up (0.41 per 1000). Among 3368 women randomized to placebo there were 10 cases of invasive breast cancer per 6991 person-years of follow-up (1.43 per 1000). *The effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established.*

Def.'s Exh. H (Evista Package Insert Revised as of Dec. 2, 1998) at 8 (emphasis added).[FN5]

FN5. The most recent data from the MORE study have shown 27 cases of invasive breast cancer in those women taking a placebo and 13 cases for those women taking raloxifene.

34. As a result of the label change, Eli Lilly gave its sales representatives a revised detailing script, which was distributed to the Evista sales force in mid-December. That detailing script instructs representatives to deliver the following message:

Dr., the FDA has recently approved a label (package insert) change for EVISTA regarding the incidence of newly diagnosed invasive breast cancer....

As you can see [from the package insert] this reflects a greater than 50% reduction in newly diagnosed breast cancer compared to placebo.

As a matter of fact, in our clinical trial of over 10,000 women of which 7,017 took EVISTA as compared to 3,368 who took placebo, there was a greater than 50% reduction in the incidence of newly diagnosed breast cancer.

Pl.'s Exh. 21 (Document re: Evista 3-year interim analysis from the Multiple Outcomes of Raloxifene Evaluation (MORE) study regarding fracture data and label change regarding breast cancer dated Dec. 11, 1998) at EV 2218 668. The sales script also provides that in the event physicians ask, "how can EVISTA show prevention of breast cancer with only 16 patients?" the appropriate response is that "10 cases of invasive breast cancer were diagnosed in the placebo group and six were diagnosed in the Evista group" and "[t]his information translates to a greater than 50% reduction in breast cancer risk." *Id.* at 672; *see also* Pl.'s Exh. 67 at EV 205 77[5] (noting that in "Q4 '98," Eli Lilly "added proactive BC information" to its core message).

35. As part of the label change, the FDA required Eli Lilly to place on the label the following statement: "The effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established." Def.'s Exh. H at 8. The December script instructed that, if representatives are asked what that sentence means, they should respond: "This is somewhat standard language included by the FDA to ensure that physicians understand that studies are ongoing and EVISTA is not indicated for the prevention of breast cancer." Pl.'s Exh. 21 at EV 2218 673. The plain language of the statement contradicts that interpretation.

2. *Eli Lilly sales representatives' call notes*

***12** 36. In light of these instructions, Eli Lilly sales representatives have repeatedly told physicians that Evista is a proven breast cancer prevention drug and a proven alternative to tamoxifen. Tr. at 230, 874-75 (Torres). From October 1998, when Nolvadex was first approved for breast cancer risk reduction, through March 1, 1999, after this suit was filed, call notes made by Eli Lilly sales representatives contain more than 500 entries in which Eli Lilly representatives report making explicit breast cancer efficacy claims about Evista. Those claims fall into the following two categories and are typified by the statements quoted below.

a. Claims that Evista has been *proven to reduce the risk of breast cancer*

- "I explained evista decreases risk of breast cancer drastically compared to placebo." (10/8/98-844401745)
- "[I] tell him that e reduces the incidence of newly diagnosed breast cancer ranging from 50 to 80%." (10/20/98-210000310)
- "[H]it him with strong evista message...he asked if we have a cancer indication or a treatment

indication...told him the indication are coming it's just a matter of time...but the data is there and is strong." (11/4/98-338007116)
• "Ev: he basically said he doesn't believe the claims Ev has made... w/ cancer (breast cancer reductions) ...need to be confident in standing up for Ev and telling him these claims are proven not suspected." (11/16/98-348606679)
• "She mentioned that Evista doesn't reduce the risk of breast cancer [sic]. I sd well doctor that is not true any longer. I then went through the MORE data and Asco data." (11/17/98-657601659)
• "Promoted breast cancer prevention need to remind her next time." (11/24/98-807602090)
• "Told [Dr.] that all pm pts are right because evista ... has been shown to reduce cancer risk." (12/4/98-615802967)
• "Evista 3 combined benefits for the prevention of all three diseases not just one." (12/4/98-736800257)
• "Told him new data on EV...now shown to reduce risk of newly diagnosed breast cancer vs placebo." (12/15/98-489006635)
• "[H]e asked does that mean you can be used for breast cancer-I said no we do not have breast cancer indication but by the fda allowing us to put this data in our pi they believe there is a defenite [sic] decrease risk." (1/11/99-848001303)
• "I told him to rest assure and to tell Pt.'s actually reducing the incidence of breast cancer." (1/20/99-848801004)
• "He said Evista will be huge once we can say for sure that it protects women against breast cancer. I said 'with all due respect, Dr. Dejarnatte, that's what the package insert now states with the change that took place in December." ' (1/25/99-761405939)
• "I told him now he can actually say with confidence that Evista actually reduces the incidence of breast cancer..." (1/26/99-848801056)
• "[P]oint out the fact that there's no 'up-in-the-air' w/ evista, because we know it reduces breast cancer, etc." (2/8/99-240003187)
***13** • "[Q]uick reminder evista builds bone, lowers lipids and reduces the risk for breast cancer...." (2/12/99-618492020)
• "Told her that EV is not a BC drug, but the BC prevention is an element of the combined benefits of the drug." (2/25/99-678008612)
• "Bottom line is why give women agent that will make them worry they could get breast cancer when can give an agent that can prevent it." (3/1/99-740210792)

Pl.'s Exh. 25 (Call Notes of Eli Lilly Representatives).

b. *Claims that Evista is proven equal or superior to Tamoxifen*

• "[E]vista 3 way-wanted to know re breast cancer data-told him the 60-80% reduction-he said what about tamox-said evista's data is better and doesn't increase risk for endometrium either." (10/5/98-578403397)
• "F [follow up]: Push tamoxifen vs evista-BC data doc needs to hear again and again-why even start pats on tamoxifen?" (10/15/98-623600314)
• "[H]e asked right away about BC, went into MORE and compared w/ Tamoxifen, we agreed that evista is a much better choice...." (11/3/98-244001904)
• "He then wanted to know if I was saying-replace Tamoxifen with Evista. I said well, no FDA approval, but most of the doctors are already doing that, what will you do? He said Tamoxifen rep already came to detail him. I said so far what you have is study on Tamox vs. placebo and Evista vs. placebo, although you can't really compare, Evista looks better and without the endo effects." (11/16/98-422406095)
• "evista-3 way combined benefit given, interested in the STAR study and the breast cancer prevention, mentioned the MORE study and that evista's reduction in incidence of newly diagnosed breast ca was greater than tamoxifen's." (11/23/98-921201870)
• "Asked if [STAR trial] will show Evista is better than Tamox. Told him already better-No endo. cancer." (12/14/98-248000538)
• "Informed him about 63% reduction of breast cancer among women who have high risk of breast cancer compared to [Tamoxifen.] He was pretty pleased with that." (12/17/98-888000151)
• "Shared with him the PI change. He also asked how that compares to Tamoxifen. Explained we are believed to build bone every bit as well, and we don't have the endometrial issues they have. Evista is clearly a better choice for many reasons." (1/8/99-587000147)
• "Evista first line ahead of tamox. for prevention." (1/12/99-281202408)
• "He talked to me about several women that the oncologists were switching from Tamoxifen to Evista. He asked me if this was ok in my opinion. I stressed breast cancer data again about reductions in pervasive type cancer and ert positive cancer. He said he guesses it makes sense but he'd be more comfortable with some studies. I started to tell him the lack of studies didn't slow him down from rxing ERT but I didn't. Maybe next time." (1/21/99-870608719)
• "Nolvadex rep had just left.....listened to her give

entire tamox detail.....gave all sorts of figures on BC.....went right in and asked him..... 'Dr Bill, why and where would you ever use Tamox over Evista? ? ? ?' /..... said he wouldn't.....no reason to with the risks of endomet cancer, which of course she DID NOT mention." (2/17/99-360201058)
***14** Pl.'s Exh. 23 (Call Notes of Eli Lilly Representatives).
37. There are some call notes from Eli Lilly sales representatives that suggest that a very small number sales representatives have told doctors that Evista has been approved or indicated by the FDA for the prevention of breast cancer. *See* Pl .'s Ex. 24. However, many other call notes indicate that representatives have informed doctors that Evista is not indicated for the prevention of breast cancer. *See, e.g.,* Pl.'s Ex. 25 (call note from 1/11/99-848001303). Moreover, one of the verbatims that was given to sales representatives specifically instructed them to tell doctors that "Evista is not approved for the prevention of breast cancer." Pl.'s Exh. 15 at EV 2609 327. Thus there is insufficient evidence to conclude that Eli Lilly sales representatives have promoted Evista as approved or indicated by the FDA for the prevention of breast cancer.
38. The entries in which the two claims about Evista were made-that Evista has been proven to reduce the risk of breast cancer and that Evista is comparable or superior to tamoxifen for reduction of the risk of breast cancer-were written by more than 170 different representatives, or approximately 17 percent of Eli Lilly's general sales force. In addition to being largely reflective of the Eli Lilly scripts, the fact that representatives recorded these messages in the business records of the company confirm that they were not inadvertent or unauthorized. Indeed, as set forth below, Eli Lilly executives and Eli Lilly's verbatims confirm that the representatives are authorized to convey these messages.[FN6] In fact, at the hearing Eli Lilly conceded that its representatives are authorized to state that raloxifene has been established to reduce the risk of breast cancer. (Tr. dated June 24, 1999 at 69, 74.) The verbatims and testimony of Eli Lilly executives also confirm, however, that Eli Lilly sales representatives have not promoted Evista as having been approved or indicated by the FDA for the reduction of the risk of breast cancer. Thus the evidence establishes that two of the three contested statements have been made by Eli Lilly representatives.

FN6. Eli Lilly emphasized at the hearing that the nearly 600 offending call notes cited by Zeneca are purportedly just a small portion of the 1.8 million total call note entries concerning Evista compiled since January 1998. The only relevant period, however, is from October 1998 forward, since that is when Zeneca entered the breast cancer risk reduction market. In any event, that Zeneca did not offer more entries does not mean that Eli Lilly representatives did not make these false claims on other occasions. In light of the detail scripts the representatives are required to follow, the testimony of Eli Lilly's executives, as well as the results of Eli Lilly's market research (described in more detail below), these hundreds of entries are appropriately representative of messages conveyed by Eli Lilly representatives on other occasions.

3. *Testimony by Eli Lilly's business executives*

39. The entries in the call notes are echoed by the testimony of three Eli Lilly executives: Denice Torres, Eli Lilly's Evista Brand leader; Newt Crenshaw, Eli Lilly's Vice President of Sales and Operations; and Garry Nicholson, Eli Lilly's Director of Oncology Business. The testimony of these executives supports the contention of Zeneca and Barr that two of the three alleged statements are being made and supports Eli Lilly's position that sales representatives have not been telling physicians that Evista has been approved or indicated by the FDA for reduction of the risk of breast cancer.
40. First, Ms. Torres testified that the "key breast cancer message" that Eli Lilly representatives should now communicate to physicians in response to unsolicited questions about Evista and breast cancer is that "in studies up to three years, Evista reduces the risk of breast cancer by greater than 50 percent," and that when a physician asks whether Evista reduces the risk of breast cancer, the representative should respond that "the data have shown and studies have shown that Evista reduces the incidence of breast cancer greater than 50 percent." Tr. at 863 (Torres). She also testified that the representatives are not directed to disclose any of the potential flaws in the MORE study or any other drawbacks which might bear on this conclusion, except for the fact that Evista is not indicated for breast cancer risk reduction. Tr. at 863-64 (Torres). Ms. Torres noted that responses by representatives to unsolicited questions from physicians are not isolated occurrences, since physicians are constantly asking a whole variety of questions depending on their level of interest. Tr. at 866 (Torres).

***15** 41. Ms. Torres likewise testified that if a physician asks what is meant by the phrase on the Evista label-"the effectiveness of Evista in reducing the risk of breast cancer has not yet been established"-an Eli Lilly rep is supposed to respond that "while Evista is not indicated for reduction in the risk of breast cancer there are data that demonstrate that Evista is effective in clinical studies in reducing the risk." Tr. at 216-17 (Torres). She also expressed satisfaction that the messages in question had been delivered by Eli Lilly representatives and that representatives continued to deliver them even after this litigation began. Tr. at 216, 874-75 (Torres).

42. Mr. Crenshaw, who is responsible for supervising Eli Lilly's primary care sales representatives, similarly testified that he would not be troubled if an Eli Lilly sales representative told a physician that the MORE data shows that raloxifene is effective in reducing the risk of breast cancer. Tr. at 186-87 (Crenshaw). Moreover, he testified that sales representatives are authorized to present data from the MORE trial without stating that "the effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established." Tr. at 177-78 (Crenshaw).

43. Finally, Mr. Nicholson testified that Eli Lilly at launch developed a program to detail oncologists concerning Evista during the first half of 1998. Tr. at 241-42 (Nicholson). The mere fact that Eli Lilly was detailing Evista to oncologists is itself telling, since Evista is not indicated for breast cancer treatment or prevention. Mr. Nicholson also noted that oncology representatives continue to respond to unsolicited questions from oncologists concerning Evista. Tr. at 262 (Nicholson).

44. Moreover, Mr. Nicholson testified that in their discussions with oncologists, Eli Lilly's oncology representatives are not prohibited from telling oncologists in response to unsolicited questions, that (i) the MORE study proves that Evista reduces the risk of breast cancer, (ii) Evista's reduction in the incidence of breast cancer is greater than tamoxifen's, (iii) the data on the Evista label demonstrates that Evista reduces the risk of breast cancer, and (iv) physicians may tell their patients that Evista reduces the risk of breast cancer. Tr. at 256-57, 259, 262, 265-66 (Nicholson).

4. *Eyewitness testimony*

45. Several Zeneca sales representatives and others have observed Eli Lilly sales representatives telling physicians and oncologists that Evista has been proven to prevent or reduce the incidence of breast cancer. For example, one Zeneca district manager testified that he overheard an Eli Lilly representative inform a physician that "the findings [of MORE] were there was a 77 percent reduction in breast cancer" for patients taking Evista. The Eli Lilly representative went on to note that "you're aware of the dangerous side effect profile of Tamoxifen." Tr. at 118 (McLellan). Another Zeneca representative overheard an Eli Lilly representative, in the presence of an Eli Lilly supervisor, tell a physician that "Evista would reduce the incidents [sic] of breast cancer." Tr. at 123 (Blair).

***16** 46. In addition, one Zeneca representative found an Evista patient brochure in a physician's office with a signed note from the Eli Lilly representative, which stated: "*New label* change includes the *Reduction* of Breast Cancer incidence-by 50%!" Tr. at 131-32 (Tirk) & Pl.'s Exh. 7 (emphasis in original). And a registered nurse working in the office of a well-known oncologist testified that an Eli Lilly representative told the nurse and the doctor that the MORE data which was soon to be released would "prove that the effectiveness of Evista had been established in breast cancer patients." Tr. at 272 (Landes). The doctor later told the nurse that the doctor "[didn't] like the way [Evista] was presented to us and I think that has been misleading." Tr. at 278 (Landes).

47. Finally, one Zeneca representative testified that last October in a doctor's office, and again at a physicians' conference in late March 1999-after this lawsuit had been filed-he observed Eli Lilly representatives repeatedly refer to clinical materials to convey the message that Evista has been shown to reduce the risk of breast cancer in women by 50 percent or greater. Tr. at 105-09, 110-11 (Centers).

5. *Eli Lilly's market research*

48. Market research commissioned by Eli Lilly likewise confirms that its representatives have been telling physicians that Evista has been proven to reduce the risk of breast cancer. As noted above, Eli Lilly's president acknowledged that, if the representatives were making breast cancer prevention claims, "you would expect" that fact to be reflected in the company's market research. Pl.'s Exh. 2; *see also* Tr. at 169 (Crenshaw).

49. According to the last Richard Day survey conducted in late November and early December 1998, physicians who were detailed by Eli Lilly representatives reported having received the following "main messages" based on their recent

detail visit from an Evista sales representative:
• "prevention of breast cancer and osteoporosis"
• "decrease of breast cancer risk"
• "prevent breast cancer"
• "lowers risk of breast cancer"
• "shown to decrease risk of breast cancer"
• "Osteoporosis prevention and breasxt [sic] cancer prevention"
• "Decreases breast cancer"
• "Very effective prevention of breast cancer"
• "it reduces breast cancer risk"
• "new data has come to show it is effective in fighting breast cancer"
• "new indication of the reduction of bc"
• "the three-year study that's out now from the FDA that says that Evista lowers the risk of breast cancer"; and
• "its [sic] shown to reduce the risk of breast cancer by 50 percent."
Pl.'s Exhs. 63 & 65; Tr. at 522, 524, 528-30 (Ross). Significantly, both the Project Manager for Richard Day and Eli Lilly's executives testified that they were satisfied with the methodology used by Richard Day and believed that the results were reliable. Tr. at 235-36 (Harenberg); Tr. at 526-27, 535 (Ross).

6. Eli Lilly's arguments with respect to two of the three *claims*

***17** 50. At trial, Eli Lilly did not meaningfully dispute that its sales representatives are making the claim that it has been established that Evista reduces the risk of breast cancer. In fact, counsel for Eli Lilly appeared to agree that Eli Lilly sales representatives have been making that claim. (Tr. dated June 24, 1999 at 69, 74.) Instead, Eli Lilly contended that it is not making claims that Evista has been proven equivalent or superior to tamoxifen for reduction of risk of breast cancer or that Evista is approved by the FDA for the reduction of the risk of breast cancer. With respect to the claim that it has been established that Evista reduces the risk of breast cancer, Eli Lilly contended that, despite the contrary language in the Evista label, the statement is not literally false.
51. At trial, Eli Lilly attempted to undercut the accuracy of the call notes by relying on declarations from doctors who were detailed by certain of its representatives. The Court has considered these affidavits in light of the fact, as explained above, that the strict rules of evidence do not apply on a motion for a preliminary injunction. Nevertheless, the affidavits do not seriously compromise the persuasive evidence that two of the three contested statements are being made. That these statements are being made is supported by numerous sources in addition to the call notes themselves. Moreover, under the circumstances of this case, in which Zeneca challenges oral statements by Eli Lilly sales representatives, memory and credibility are critical. The absence of any opportunity for cross-examination renders these out-of-court statements of limited value. Eli Lilly had the opportunity to introduce the depositions of any of these doctors but did not. It is unlikely that a doctor would be able to recall what a particular sales representative did or did not say in a two or three minute conversation that took place several months ago. The affidavits do not purport to recount all of the relevant details of what was said in the conversations. Def.'s Exhs. T-4 through R-5. Under the circumstances, the contemporaneous call notes themselves, which fall under the well-recognized business records exception to the hearsay rule, are more persuasive evidence of what was said.
52. It is also significant that Eli Lilly has not made any representation that it will not make at least the claim that it has been established that Evista reduces the risk of breast cancer, nor has it undertaken to instruct its representatives not to make that statement. Indeed, Eli Lilly maintains that its representatives are authorized to state that it has been established that Evista reduces the risk of breast cancer.
53. In sum, for purposes of this preliminary injunction motion, Zeneca has met its burden of proving that Eli Lilly representatives are communicating the claims that Evista has been proven to reduce the risk of breast cancer and that Evista is comparable or superior to tamoxifen in reducing the risk of breast cancer.

E. Eli Lilly's claims about Evista are false

***18** 54. Eli Lilly's witnesses acknowledge that Evista is not indicated by the FDA for the reduction of the risk of breast cancer, Tr. at 199-200 (Crenshaw); Tr. at 265 (Nicholson), and thus that if its representatives are making that claim, it is false. However, the Court has found that there is insufficient evidence that Eli Lilly's representatives are making such a claim. Eli Lilly also concedes that Evista has not been tested against, much less proven comparable or superior to, tamoxifen. Tr. at 180, 208-09 (Crenshaw); Tr. at 740, 771, 786 (Cummings). That claim, too, is false and the evidence indicates that Eli Lilly's representatives are making that claim.
55. With respect to the remaining claim, Eli Lilly

contended at the hearing that Evista has been proven to reduce the risk of breast cancer. As set forth below, however, the FDA, as well as numerous other experts in the field of clinical oncology, have reviewed the relevant data and reached the nearly unanimous conclusion that, while Eli Lilly's data is promising, it does not prove that Evista reduces the incidence of breast cancer. Given the state of the evidence, and particularly in view of the highly regulated nature of drugs and their indicated uses, at this time there is not sufficient evidence to conclude that raloxifene has been proven to reduce the risk of breast cancer. Thus the claim that raloxifene has been proven to reduce the risk of breast cancer is a false claim in light of current scientific evidence.

1. *The conclusions of the FDA*

56. By statute, the FDA is the agency that is responsible for determining the safety and efficacy of prescription drugs in this country. *See* 21 U.S.C. § 393(b). The parties' experts and other witnesses testified, and the Court finds, that the FDA is a recognized authority and has expertise in assessing the results of clinical drug tests. Tr. at 372 (Lewis); Tr. at 427-29 (Carlson); Tr. at 740-41 (Cummings); Tr. at 1102 (Dere); Lippman Dep. Tr. at 84.

57. The FDA has reviewed all the breast cancer data from the MORE trial and has met with Eli Lilly's study investigators and scientists in response to Eli Lilly's request that the FDA evaluate whether the MORE data proves that Evista reduces the risk of breast cancer and would support such an indication for Evista. Based on its review, the FDA has repeatedly determined and communicated to Eli Lilly in Meeting Minutes that the MORE study does not and cannot prove that Evista reduces the risk of breast cancer. The Court finds the FDA's conclusions and reasoning highly persuasive.

58. One of the basic flaws cited by the FDA concerning Evista and breast cancer prevention is that the MORE study was intended as an osteoporosis study, not a breast cancer trial. To that end, the "primary objective[ ]" set forth in the MORE study protocol was "to establish the effects of long-term treatment ... with raloxifene ... on the rate of new vertebral fractures in osteoporotic postmenopausal women ...." Def.'s Exh. P (Protocol H3S-MC-GGGK(e) [MORE study protocol]) at EV 013 837. Among the last of many secondary endpoints, the protocol instructed the investigators to gather data on the "risks of breast and endometrial cancer." *Id.* But the sole purpose of gathering this data was to find out whether long-term use of Evista was safe in the breast and would not increase a woman's risk of developing breast cancer. Tr. at 411-14 (Carlson); Tr. at 618-19, 622-25, 722-23, 728-29 (Cummings). The protocol was not designed, nor was the study intended, to determine if Evista would be efficacious in reducing the risk of breast cancer.

***19** 59. Women were not selected for the MORE study based on their risk of developing breast cancer, nor were they randomized between the raloxifene and the placebo arms of the MORE study based on breast cancer risk factors. Tr. at 730 (Cummings); Tr. at 1146-47 (Scott).

60. Months before the Evista launch, Eli Lilly itself anticipated this point and acknowledged the danger of relying on the MORE data to support a breast cancer risk reduction claim. For example, Eli Lilly's internal instructions to its oncology representatives concerning Evista declared:

Evista was not associated with an increased risk for breast cancer.... However, it is premature to draw conclusions about Evista as a cancer preventive agent. To do so would be a disservice to the millions of women who fear the disease.

Pl.'s Exh. 26 at EV 2446 40. Eli Lilly's Director of Oncology Business, Mr. Nicholson, testified that this statement is equally true today. Tr. at 250-51 (Nicholson).

61. The FDA's decision to allow Eli Lilly to include the interim data from MORE in the safety section of Evista's label does not, as Eli Lilly contends, demonstrate the FDA's acceptance of the MORE study as proof that Evista reduces the risk of breast cancer. In August 1997, in response to Eli Lilly's first such inquiry, the FDA advised Eli Lilly that the MORE data did not and probably never would support a breast cancer efficacy claim:

The data provided appear to be grossly insufficient to support a claim that raloxifene reduces breast cancer risk. Despite the summary nature of the information provided, it is unlikely that more information will improve the acceptability of the methodology or the credibility of the data used by the sponsor to conclude that raloxifene reduces the risk for breast cancer.

Pl.'s Exh. 38 (FDA Document-Center for Drug Evaluation and Research Approval Package-Evista, Medical Officer Consult dated Aug. 6, 1997) at EV 413 411. Among other criticisms, the FDA reviewer noted that the study lacked proper controls and that to support this claim Eli Lilly would need to develop a protocol in which "breast cancer incidence is a primary endpoint." *Id.*

62. In the fall of 1997, the FDA told Eli Lilly that "it is *not* acceptable to include language in the label that

'there was a statistically significant reduction in the frequency of newly diagnosed breast cancer in raloxifene-treated women compared to placebo' because "[a]cceptance of this claim would effectively provide [Eli Lilly] with a second indication for raloxifene...." Pl.'s Exh. 40 (Breast Cancer Statement from FDA) at EV 651 1055; *see also* Pl.'s Exh. 38. Later, in March of 1998, the FDA indicated that Eli Lilly could apply for a label change to reflect the interim data from the MORE trial. In doing so, however, the FDA's reviewer reiterated "[t]here are questions about the reliability of the [MORE] data"; that "[i]t is expected that it will not be possible to retrospectively obtain sufficient information to justify a claim related to breast cancer prevention"; and that if Eli Lilly were to reference the MORE study, the label would have to state that "[t]he effectiveness of raloxifene in reducing breast cancer has not been established." Pl.'s Exh. 41 (Medical Officer Review of Raloxifene Adjudication Data dated Mar. 2, 1998) at EV 415 2059.

***20** 63. In December 1998, the FDA approved a change in the safety section of Evista's label which allowed Eli Lilly to refer to the MORE breast cancer data as part of Evista's safety profile. In approving this limited change, however, the FDA again made clear that Eli Lilly could not use the MORE data to suggest that Evista has been shown to reduce the risk of breast cancer or that the drug has been approved for that purpose. Thus, Eli Lilly was able to report on the label the combined interim data from MORE and its other osteoporosis trials as follows:

Independent review has determined that 16 cases (raloxifene and placebo combined) represented newly-diagnosed invasive breast cancer. Among 7017 women randomized to raloxifene, there were 6 cases of invasive breast cancer per 14,605 person-years of follow-up (0.41 per 1000). Among 3368 women randomized to placebo there were 10 cases of invasive breast cancer per 6991 person-years of follow-up (1.43 per 1000).

But to warn physicians that this data was safety information only, the FDA required Eli Lilly to state expressly in the label that "[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established." Def.'s Exh. H at 8.

64. After the label change, in January 1999, Eli Lilly representatives attended a meeting at the FDA in an attempt to persuade the FDA's Oncology Division that more recent breast cancer data from the MORE trial-a total of 27 cases of invasive breast cancer on placebo and a total of 13 cases on raloxifene-proved that Evista reduces the risk of breast cancer and would support a contemplated supplemental new drug application ("sNDA") for an indication for the reduction of the risk of breast cancer. Prior to the meeting, Eli Lilly posed the following question to the FDA: "We believe the data presented in this briefing document provide compelling evidence that raloxifene reduces the incidence of breast cancer in post-menopausal women with osteoporosis.... Does the Agency concur ... ?" The FDA responded as follows:

We have concerns about the credibility of the finding (fewer cases on the raloxifene arms compared to the placebo arm). The following issues represent critical problems in the clinical trial design that probably cannot be addressed retrospectively.

Pl.'s Exh. 45 (Meeting Minutes for Jan. 28, 1999 Meeting, Questions for Discussion with FDA Response) at EV 2383 55. The FDA then proceeded to identify various flaws in the MORE trial, which went beyond the fact that "[b]reast cancer incidence was not prospectively defined as an endpoint." *See id.* at EV 2383 55-57.

65. Based on statements made by FDA officials at the January 1999 meeting, Eli Lilly's scientists concluded that "nothing could be done to salvage the MORE Study for a breast cancer indication." Tr. at 956, 959-60 (Eckert); Pl.'s Exh. 46 at EV 2386 1818. Shortly after the FDA issued these findings, Eli Lilly decided to terminate the MORE trial. Tr. at 962 (Eckert); Pl.'s Exh. 46 at EV 386 1818.

***21** 66. In response to this termination, the FDA urged Eli Lilly on March 11, 1999 to continue to follow up on the MORE patients, noting that such data "will provide important supportive information in conjunction with the STAR data for a sNDA submission for raloxifene to reduce the incidence of breast cancer." Pl.'s Exh. 46 at EV 2386 1820. Eli Lilly then proposed to the FDA that it would commence a "new" study called "Continuing Outcomes of Raloxifene" or CORE, using as many of the women enrolled in the MORE study who would agree to participate. Like MORE, CORE will continue to have both a raloxifene and a placebo arm and will last four years. Eli Lilly made substantial changes in the way the trial will be conducted. For example, the incidence of breast cancer is now the primary endpoint of the study; new study participants will be given a GAIL risk assessment; the appropriate statistical analysis for the breast cancer data is set forth in the protocol; and the protocol requires annual breast physical examinations. Tr. at 751-53 (Cummings); Tr. at 938-40, 967-68 (Eckert).

67. Nonetheless, the FDA has since determined that MORE-even when coupled with the CORE extension-still will not prove that Evista reduces the risk of breast cancer. In early April, Eli Lilly submitted the CORE protocol to the FDA and posed

the following question:
We believe that achievement of statistical significance with the stated endpoints in the enclosed proposed draft CORE protocol will confirm, along with the data provided to date from the 3-year MORE protocol, that Evista does reduce the incidence of invasive breast cancer after long term treatment in postmenopausal women with osteoporosis. Does the Agency concur with these conclusions?
Pl.'s Exh. 46 at EV 2386 1872. On April 16, 1999 the FDA responded as follows:
No, we do not.
The primary endpoint should be the occurrence of all invasive breast cancer.
Analyses that demonstrate long-term clinically and statistically significant differences between patients treated with raloxifene and placebo in the incidence of breast cancer will provide supportive evidence of efficacy. Data from a prospective randomized trial of raloxifene in which the reduction in the incidence of breast cancer is the primary endpoint will be needed, such as data from the STAR trial.
Pl.'s Exh. 47 (Facsimile from FDA to Eli Lilly dated Apr. 16, 1999) at EV 2736 000003.
68. The FDA recognized that the "CORE study will address some of the problems identified in the MORE study with respect to the breast cancer endpoint, such as poorly documented baseline status, short follow-up, and lack of consistent follow-up." FDA went on to explain, however, that "[d]espite these improvements, it is unlikely that data from [MORE] and CORE will be sufficient" to support an application for a breast cancer risk reduction indication. *Id.* at EV 2736 000002. Accordingly, the FDA told Eli Lilly that based solely on the combined data from MORE and CORE, it would not support a new drug application submission even for a limited indication "for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis." *Id.* at EV 2736 000003-04.
***22** 69. Representatives of Eli Lilly met again with the FDA on May 11, 1999. In the minutes of that meeting prepared by the FDA, which Eli Lilly received on June 4, 1999, the FDA reiterated that MORE and CORE cannot prove that Evista reduces the incidence of invasive breast cancer in postmenopausal osteoporotic women and told Eli Lilly once again that it would not support an sNDA based solely on the results of those studies. Specifically, Eli Lilly had asked the FDA:
We believe that achievement of statistical significance with the stated endpoints in the enclosed proposed draft CORE protocol will confirm, along with the data provided to date from the 3-year MORE protocol, that Evista does reduce the incidence of invasive breast cancer after long term treatment in postmenopausal women with osteoporosis. Does the Agency concur with these conclusions?
The FDA responded, consistent with its response on every previous occasion: "No, we do not." Def.'s Exh. K-9 (May 11, 1999 Meeting Minutes) at 3.
70. The FDA suggested several alternatives for Eli Lilly to consider, involving various combinations of MORE/CORE, the STAR trial and an Eli Lilly trial called RUTH, which is currently proposed to determine the cardiovascular effects of raloxifene. Alternatively, if Eli Lilly decided to pursue a "limited indication" for the reduction of the incidence of invasive breast cancer in postmenopausal women, "[i]t is possible that MORE/CORE plus RUTH will be sufficient to demonstrate a reduction in the incidence of invasive breast cancer" but the FDA suggested that Eli Lilly add breast cancer risk reduction as a primary or co-primary endpoint of the RUTH trial. Def.'s Exh. K-9 at EV 2736 000367; Tr. at 979-81 (Eckert). Thus, the FDA has made clear that MORE-even when coupled with the CORE extension-will not suffice as a basis for proving the efficacy of raloxifene in the reduction of risk of breast cancer.
71. None of the Evista trials Eli Lilly plans to conduct or participate in will be completed in the near future. CORE is supposed to last four years. RUTH is expected to last five years. Enrollment in STAR began just last month and the study will not be completed for at least five years. Tr. at 761 (Cummings); Tr. at 982 (Eckert). Thus, while the MORE results may be promising, it has not yet been shown to be sufficient proof that Evista reduces the risk of breast cancer.

3. Other experts have agreed that MORE does not *prove that Evista reduces the risk of breast cancer*

72. There is other support for the conclusion that it is premature to find that raloxifene reduces the risk of breast cancer.
73. During the testimony of the experts on both sides in this case, it became clear that the issue of whether the MORE trial has proven the efficacy of raloxifene in reducing the risk of breast cancer has been considered by several well-respected third-party organizations in the field of clinical oncology. Experts on both sides acknowledged that these organizations have determined that it is premature to conclude that Evista reduces the risk of breast cancer. Tr. at 331-34 (Lewis); Tr. at 430-41 (Carlson); Tr. at 668, 702-07 (Cummings).

***23** 74. In May of this year, a special committee of the American Society of Clinical Oncology ("ASCO"), issued a report based on its assessment of the propriety of using tamoxifen or raloxifene for reducing the risk of breast cancer. The Committee, comprised of leading experts in several fields, analyzed all research conducted on tamoxifen and raloxifene from 1990 through 1998. In response to the question, "Is there strong or credible evidence to conclude that raloxifene will reduce the risk of developing breast cancer" the Committee responded "it is premature to recommend raloxifene use to lower the risk of developing breast cancer outside of the clinical trial setting." Tr. at 430-33 (Carlson); Tr. at 668, 702 (Cummings).

75. Significantly, both parties' experts have testified that ASCO is the premier clinical oncology organization in the world. They also agreed that the conclusions of the ASCO committee, like any other ASCO publication, are entitled to great weight. Tr. at 292-93 (Lewis); Tr. at 394-95 (Carlson); Tr. at 705-07 (Cummings); Tr. at 1105 (Dere); Lippman Dep. Tr. at 85-87.

76. Similarly, a committee of the National Comprehensive Cancer Network ("NCCN"), a prestigious consortium of major cancer centers throughout the United States, has recently prepared a draft of breast cancer prevention guidelines. The draft guidelines conclude that "insufficient data are available to make definitive statements regarding the benefit or toxicity of raloxifene." Tr. at 434-35 (Carlson). The parties' experts agree that, like ASCO, NCCN is an expert body in the field of clinical oncology and that its guidelines are authoritative in the field. Tr. at 395-97 (Carlson); Lippman Dep. Tr. at 83-84.

77. At trial, Eli Lilly attempted to downplay the significance of the ASCO and NCCN guidelines-even though Eli Lilly's expert Dr. Steven Cummings served as a member of the ASCO Committee for a period of time, Tr. at 693-94, 697, 701 (Cummings)-because the organizations purportedly did not have the full data from the MORE study, which ran to a median of 40 months, or the recently published article in JAMA, written by doctors and other experts affiliated with the MORE study, which concluded that Evista reduces the risk of breast cancer in postmenopausal osteoporotic women after 40 months of treatment. However, there is no dispute that ASCO and NCCN had data through 33 months from the MORE study, Tr. at 708-09 (Cummings), a significant amount of data. In addition, the ASCO report made clear that the grounds for its conclusion were that "this study was designed as an osteoporosis trial; breast cancer risk was not specifically addressed at entry, nor was breast cancer development a primary outcome measure." The Committee also noted that the MORE finding was based on a small number of events. Tr. at 709 (Cummings). These deficiencies are not cured by an additional seven months of MORE data or by the publication of the JAMA article.

***24** 78. As for the NCCN, the expert who testified on behalf of Zeneca, Dr. Robert Carlson, is the Chairman of the Committee charged with drafting those guidelines. As set forth below, he is of the firm conclusion, even after having reviewed the 40-month data and the JAMA article, that raloxifene has not been proven to reduce the risk of breast cancer.

79. As indicated by the experts' testimony, two other organizations, the NCI and the NSABP-which are jointly sponsoring the upcoming STAR trial-have likewise made clear that the efficacy of raloxifene in reducing the risk of breast cancer has not yet been proven. In the model consent form for the STAR study, which was prepared by scientists and about which both Zeneca and Eli Lilly had the opportunity to comment, participants in STAR are advised that the very purpose of the study is to try to find an answer to the following three questions:

- "Is raloxifene, also known by the trade name Evista, effective in reducing the incidence of breast cancer in women who are at increased risk for developing breast cancer?"
- "If it is effective, how does raloxifene compare to tamoxifen, also known as Nolvadex, in reducing the incidence of breast cancer?" and
- "How do the side effects (good and bad) of raloxifene and tamoxifen compare?"

Tr. at 324-27, 331-34, 357 (Lewis); 436-38 (Carlson); Pl.'s Exh. 34 (NSABP Protocol P-2, Study of Tamoxifen and Raloxifene (STAR) for the Prevention of Breast Cancer) at 51. The model consent form also clearly states that *"[t]he FDA and the [Canadian Health Protection Branch] consider the use of raloxifene for reducing the risk of breast cancer to be experimental at this time."* Pl.'s Exh. 34 at 51 (emphasis added); Tr. at 333-34 (Lewis).

80. The Court was also persuaded by the testimony of two expert oncologists and one biostatistician offered by Zeneca. These witnesses-whom the Court finds to be both qualified and credible-cited numerous persuasive reasons why the data from the MORE trial, though encouraging, do not prove that Evista reduces the risk of breast cancer.

81. Dr. Robert Carlson is a professor of medicine and oncologist at Stanford University with extensive experience and expertise in the area of breast cancer treatment and research as well as the conduct and design of clinical trials. He was a principal

investigator for the BCPT and is one of the investigators for the STAR trial. Tr. at 389-93 (Carlson). Having reviewed all of Eli Lilly's breast cancer data, including the results of the nine other osteoporosis studies conducted for Eli Lilly, Dr. Carlson testified that "the data is insufficient to conclude definitively that raloxifene decreases the incidence of breast cancer." Tr. at 398-402 (Carlson).

82. Dr. Carlson noted, first, the inconsistencies between the MORE results and those in the other nine Eli Lilly raloxifene trials. Dr. Carlson concluded that if the MORE findings had truly established that Evista reduces the risk of breast cancer to the degree claimed by Eli Lilly, one would have expected at least a trend in the same direction, if not a statistically significant difference, in the nine pooled studies of some 3,000 patients. No such trend is evident in the data. Tr. at 402-11 (Carlson).

***25** 83. With respect to the MORE study itself, Dr. Carlson identified several flaws, both in the design of the protocol and the analysis of the data. These flaws include the fact that MORE was designed primarily as an osteoporosis study and breast cancer appeared among several other safety-related issues in the seventh secondary endpoint of the study. In addition, the MORE protocol did not articulate a prospectively defined method for collecting and analyzing the breast cancer data in particular. Tr. at 411-14, 452-54 (Carlson). As Eli Lilly acknowledged, the statistical analysis contained in the MORE protocol was a general one specified for all of the safety endpoints in the trial. Tr. at 733 (Cummings); Tr. at 937, 941 (Eckert).

84. Dr. Carlson also explained that in a properly designed breast cancer trial such as the BCPT or STAR, it is crucial to recruit patients with a high risk of breast cancer to ensure a sufficient number of overall breast cancer events. Without an adequate number of cases, he opined, one cannot rule out the possibility that the results are due to chance. To that end, Dr. Carlson observed that a properly designed breast cancer study should assess patients for breast cancer risk prior to entry in the study using the GAIL risk assessment model, and patients should be equally randomized between the two arms of the study with respect to the full array of breast cancer risk factors. MORE failed to follow this procedure. Tr. at 415-19, 455-57, 467-68 (Carlson).

85. Dr. Carlson also identified diagnostic flaws in the protocol that cast doubt on the MORE breast cancer results. Tr. at 650-51, 732 (Cummings); *see also* Tr. at 111-22 (Dere). Finally, Dr. Carlson observed that women in the MORE study were permitted to take estrogen, which many believe increases the risk of breast cancer and may thus have confounded the results. Tr. at 419-27 (Carlson).

86. Dr. Jerry Lewis, formerly Chief of the Hematology and Oncology Division at the University of California, Davis, and now Zeneca's Senior Medical Director for Oncology, also testified. Dr. Lewis has taught and practiced in the area of clinical oncology and also has extensive experience in the design and analysis of clinical drug trials. Tr. at 290-95 (Lewis); Pl.'s Exh. 77.

87. Dr. Lewis testified convincingly to the same list of criticisms as Dr. Carlson. Tr. at 334-46 (Lewis). He specifically noted that the study population in the MORE trial were women with osteoporosis, who tend to be at low risk for breast cancer. Tr. at 337-38 (Lewis). He also opined that Evista has "not been proven to be efficacious in reducing the incidence of breast cancer." Tr. at 328 (Lewis).

88. Finally, Zeneca offered the expert testimony of Dr. Mark Scott, a biostatistician with extensive experience in the design and analysis of clinical drug trials. Dr. Scott responded to Eli Lilly's argument that the many flaws in the MORE trial may be overlooked because the breast cancer results in MORE were statistically significant at a level of p =.000005. A p value of less than .05 typically is required for a finding of statistical significance in a clinical trial.[FN7]

FN7. Under typical circumstances, where the variable in question is the primary endpoint of the study, a p value of .05 means that the odds are one in 20 that the result in question is due to chance. On its face, a p value of .000005 means that the odds are five in one million that the results in question are due to chance.

***26** 89. Dr. Scott explained that because breast cancer risk reduction was not the primary endpoint of the MORE trial, and there was no pre-specified statistical plan for analyzing breast cancer data, it is inappropriate to use a p value of .05 as a benchmark to assess the statistical significance of the MORE breast cancer data. Rather, to ensure that the results in question were not due to chance, Dr. Scott opined that the appropriate p value should be adjusted to take into account the fact that breast cancer risk reduction was a secondary endpoint and just one of hundreds of statistical tests performed in the MORE trial. Tr. at 1143-45 (Scott).

90. Dr. Scott made that adjustment, using the well-established formula, acknowledged by Eli Lilly's witnesses, Tr. at 645 (Cummings), of dividing the p value of .05 by the number of tests conducted.

According to the lead MORE investigator, Eli Lilly's expert Dr. Steven Cummings, 400 safety tests alone were conducted in MORE. Tr. at 646 (Cummings). Using that number, which did not even take into account the non-safety statistical analyses performed on the MORE data, Dr. Scott concluded that the appropriate p value to determine statistical significance was .000125. Tr. at 1144-45 (Scott).

91. Although the MORE trial's breast cancer results still achieved statistical significance using that figure, Dr. Scott's testimony illustrated the significance of the fact that the MORE trial had relatively few cases of breast cancer. As previously noted, in MORE there were 40 total cases of invasive breast cancer; this compares with 264 cases in the BCPT. Tr. at 322-23 (Lewis). Dr. Scott explained that, given the low number of overall breast cancer cases reported to date in the MORE trial, the addition of only five more cases on the raloxifene arm of the study-without a corresponding increase on the placebo arm-would render the result on which Eli Lilly now relies statistically insignificant. Tr. at 1145 (Scott). Dr. Scott testified to a number of hypothetical scenarios under which those five additional cancers on the raloxifene arm could occur. Tr. at 1146-48 (Scott).

92. Dr. Scott's conclusion is that the MORE data "are intriguing but they are not the stuff of proof." Tr. at 1167 (Scott).

93. Under these circumstances, the Court credits Dr. Scott's testimony that, because of the large number of analyses performed by Eli Lilly on the MORE data and the small overall number of breast cancer cases observed in the trial, the p value in the MORE study is insufficient to show that the MORE study proves that raloxifene reduces the risk of breast cancer.

F. Eli Lilly's rebuttal

94. Eli Lilly maintains that Evista has been proven to reduce the risk of breast cancer. In support of its position, Eli Lilly cites (i) its own interpretation of what the FDA has communicated to Eli Lilly with respect to the MORE data, (ii) the testimony of three witnesses, all of whom are involved with the MORE study, and (iii) the peer-reviewed article about the MORE results recently published in JAMA. As set forth below, these materials fail to rebut Zeneca's showing on the merits.

1. *The dialogue between Eli Lilly and FDA*

***27** 95. First, Eli Lilly maintains that the FDA has declined to approve a breast cancer risk reduction claim on the basis of the MORE data not because it considered the MORE study to be flawed, but merely because the FDA requires two well-controlled clinical trials before approving a drug as safe and effective. In light of the FDA correspondence described above, Eli Lilly's position is not tenable. The approval of a risk reduction indication for tamoxifen on the basis of the BCPT and supporting evidence makes clear that FDA will approve drugs on the basis of one large-scale clinical study with supporting evidence. Tr. at 315-16 (Lewis); Tr. at 1151 (Scott). Indeed, Congress has made clear, and the FDA has acknowledged, that the FDA may base a finding of efficacy on one adequate and well-controlled clinical investigation along with confirmatory evidence. *See* 21 U.S.C. § 355(d); *see also Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products ("Guidance for Industry")*, U.S. Dep't of Health & Human Services, Food & Drug Administration, May 1998, at 12-13.

96. Eli Lilly also contends that the statement the FDA required it to put on the label-"[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established"-is fdA'S way of communicating that Evista has been proven efficacious but is not yet indicated for breast cancer risk reduction. Tr. at 216, 850 (Torres); Tr. at 917 (Eckert); 1004-05 (Harenberg). This argument ignores the plain meaning of the word "established" and is also at odds with some of the testimony of Eli Lilly's own witnesses. For example, Dr. Cummings conceded that the statement means, at a minimum, that the efficacy of Evista in reducing the risk of breast cancer has not yet been proven to the satisfaction of the FDA. Tr. at 631-32, 638-39 (Cummings). Moreover, Eli Lilly's interpretation is contrary to the plain meaning of the FDA documents. Eli Lilly's witnesses simply disagree with the FDA or with the statement. Lippman Dep. Tr. at 158; Tr. at 1097-98 (Dere). [FN8]

FN8. One Eli Lilly executive, who has attended meetings of Eli Lilly's Raloxifene Advisory Board, which is composed of Eli Lilly and non-Eli Lilly scientists, conceded at his deposition that he understood Eli Lilly cannot make a breast cancer risk reduction claim for the drug because "[i]t's not a proven claim." Tr. at 238 (Harenberg). The executive's attempts at trial to explain away his prior deposition testimony were

unconvincing, especially since he agreed at trial that Eli Lilly cannot make claims that Evista prevents breast cancer. Tr. at 1004-08 (Harenberg).

97. Eli Lilly also suggests that the dialogue with the FDA is still ongoing and that the findings and opinions set forth in the January 1999 minutes with respect to MORE, and the May 1999 minutes with respect to MORE and CORE, do not reflect the agency's last word on the subject or are an incorrect recitation of the FDA's position. This argument is contradicted by the FDA's repeated statements over a two-year period. And whether or not the dialogue is ongoing, the FDA has made abundantly clear that MORE-either alone or in conjunction with CORE-does not and cannot prove that Evista reduces the risk of breast cancer. That is why Evista's label states that the effectiveness of Evista in reducing the risk of breast cancer has not yet been established and why the FDA will require Eli Lilly to rely on data generated by STAR, RUTH or both in any application for a breast cancer risk reduction indication for Evista.

2. *Eli Lilly's expert witnesses*

***28** 98. Eli Lilly also offered the testimony of three distinguished experts, all of whom, however, are directly associated with the MORE study and have an interest in demonstrating its scientific significance: Dr. Marc Lippman, head of the Lombardi Cancer Center at Georgetown University, Dr. Steven Cummings, Professor of Epidemiology and Biostatistics at the University of California, San Francisco, and Dr. Steven Eckert, an Eli Lilly statistician. Their testimony supports the promising nature of the MORE data with respect to breast cancer risk reduction. However, their testimony is insufficient to persuade the Court that Evista has been proven to reduce the risk of breast cancer.

99. Dr. Lippman is a distinguished oncologist who is a member of Eli Lilly's Oncology Advisory Board, a member of the breast cancer adjudication committee for the MORE study, and a coauthor of the recently published JAMA article concerning raloxifene and breast cancer. Lippman Dep. Tr. at 13, 51-52, 54-56; Tr. at 1106-07 (Dere).

100. Dr. Lippman opined only that a median of 40 months of treatment with raloxifene reduces the risk of newly diagnosed breast cancer in postmenopausal women with osteoporosis-a much narrower statement than the blanket risk reduction claim that has been made by Eli Lilly sales representatives and that Zeneca seeks to enjoin. Dr. Lippman conceded that, based on the existing data and given the patient population in the MORE study, one cannot draw the same conclusion with respect to the female population at large. Lippman Dep. Tr. at 74, 76-79. Notably, this testimony was confirmed by Eli Lilly's Dr. Will Dere, who acknowledged that the statement "Evista offers proven reduction of breast cancer" without any qualifiers "would not be right as a single sentence for Eli Lilly to state that." Tr. at 1108-09 (Dere). Dr. Dere also agreed that it would be an "overstatement" to say that Evista decreases breast cancer by 70 percent, without any qualifiers. Tr. at 1109-10 (Dere).

101. Dr. Lippman also candidly acknowledged that although he is convinced that the MORE data is accurate and proves to a reasonable degree of medical certainty that raloxifene reduces the risk of breast cancer among postmenopausal osteoporotic women, other physicians could look at the data from the MORE study and conclude that the data are not sufficient to prove that raloxifene reduces the risk of breast cancer. Lippman Dep. Tr. at 62-63, 168-72. As Dr. Lippman explained:

I believe that it is perfectly appropriate, as happens every single day in the verification of new agents, that some physicians become convinced of something before others do.... I think that right-minded physicians based on data can come to conclusions at a different rate. And I would not-this is important to me. I would not dispute that another physician could look at these data and say they are interesting, but I am not persuaded yet. I would not myself change my practice. I think that's absolutely the way medicine changes over time.

***29** Lippman Dep. Tr. at 62-63.

102. Dr. Cummings is the primary investigator for the MORE trial, as well as a member of Eli Lilly's Raloxifene Advisory Board. Tr. at 598, 682-84, 690-92 (Cummings).

103. Dr. Cummings opined that raloxifene reduces the incidence of breast cancer only in postmenopausal women, a narrower claim than that at issue here. Tr. at 712-13. Dr. Cummings' testimony also indicated that the participants in the MORE study may have been at lower risk for breast cancer than the participants in the BCPT trial based on the relative bone density of the two groups. Tr. at 720-21, 739 (Cummings).

104. While Dr. Cummings was plainly convinced of the significance of the results of the MORE study as it relates to the reduction of the risk of breast cancer, he is interested in that conclusion and his views are not shared by the FDA or other disinterested organizations.

105. Eli Lilly also relied on the testimony of Dr. Stephen Eckert, a senior Eli Lilly statistician, who opined that Evista "has clearly been statistically proven in the MORE trial to reduce the incidence of breast cancer." Tr. at 932 (Eckert). He agreed, however, that, given the small number of breast cancer events in the study, a small shift in the number of cases would have an enormous impact on the p value and could undercut the statistical significance of the interim results. Tr. at 975-76 (Eckert).

3. *The JAMA article*

106. Finally, Eli Lilly relies heavily on the fact that a peer-reviewed article concerning the MORE study breast cancer results was published in the June 16, 1999 issue of JAMA. The JAMA article, which is co-authored by Drs. Cummings, Eckert, and Lippman, among others, sets forth the authors' narrow conclusion that "a median of 40 months of treatment with raloxifene decreases the risk of newly diagnosed breast cancer in postmenopausal women who have osteoporosis and who have no prior history of breast cancer." Tr. at 712 (Cummings); Def.'s Exh. L-9 at 2196. Again, this is a narrower claim than the blanket statement being made by Eli Lilly sales representatives.

107. The article does not state that raloxifene has been or even may be proven to reduce the risk of breast cancer in any other segment of the female population. Nor does it definitively conclude that Evista has been proven to reduce the risk of breast cancer in the population that was tested. To the contrary, the authors concede that there is no data that confirms whether the existing results will continue to be seen and that "the MORE trial is continuing to assess the effectiveness and safety of longer term use of raloxifene" in postmenopausal osteoporotic women. Def.'s Exh. L-9 at 2196; Tr. at 664 (Cummings); Lippman Dep. Tr. at 66-67, 75.

108. Given Eli Lilly's reliance on this publication, there was extensive testimony about the significance of the peer review process and whether that process, in and of itself, signifies some form of scientific "proof." It is plain that it does not. Both parties' experts explained that peer reviewers as a rule are given only the manuscript of the article and nothing else. Eli Lilly's own experts conceded that this was true in the case of the JAMA article. Tr. at 393-94 (Carlson); Tr. at 765 (Cummings); Lippman Dep. Tr. at 79-81.

***30** 109. The peer reviewers at JAMA were not given the MORE protocol and thus were not in a position to assess the flaws in the MORE study design as a breast cancer trial. Nor were they given the results of the nine other Evista trials which failed to demonstrate that Evista reduces the risk of breast cancer. Finally, the peer reviewers were not given the FDA's comments concerning the inadequacies of the MORE results. Tr. at 765-66 (Cummings); Tr. at 990-91 (Eckert).

110. In any event, the mere fact of publication of a peer-reviewed article does not prove that the claim in question is true. Indeed, the FDA has stated that "[t]here are ... reasons to be skeptical of the conclusions of published reports of studies. Experience has shown that such study reports do not always contain a complete, or entirely accurate, representation of study plans, conduct and outcomes.... [I]ncompleteness, lack of clarity, unmentioned deviation from prospectively planned analyses, or an inadequate description of how critical endpoint judgments or assessments were made are common flaws. Typically, journal article peer reviewers only have access to a limited data set and analyses, do not see the original protocol and amendments, may not know what happened to study subjects that investigators determined to be non-evaluable, and thus may lack sufficient information to detect critical omissions and problems." *Guidance for Industry* at 17.

111. In sum, though the MORE data are promising and may in the future be proven to measure accurately the efficacy of raloxifene in reducing the incidence of breast cancer in some segment of the population, Evista has not yet been proven to reduce the risk of breast cancer. Based on all of the evidence, the two claims that Eli Lilly has been making for Evista-that it has been established that Evista reduces the risk of breast cancer and that Evista has been proven comparable or superior to tamoxifen for reduction of the risk of breast cancer-are literally false.

G. The harm to Zeneca, Barr, and the public

112. Zeneca's witnesses testified to the substantial negative impact of Eli Lilly's actions on Zeneca. Ms. Anson testified credibly that "Zeneca has invested an enormous amount in tamoxifen over the last 20 years in research and development," and that this investment has been jeopardized by Eli Lilly, as has Zeneca's reputation and goodwill with physicians. Tr. at 68 (Anson). Ms. Anson also highlighted the fact that because the breast cancer prevention market is just now being created by Zeneca, Eli Lilly's actions

have had a pernicious effect on Zeneca's launch and the marketplace itself, if not immediately then as a long term matter. Tr. at 100 (Anson). These are, according to the uncontradicted testimony of Ms. Anson, damages that Zeneca cannot quantify. Tr. at 70 (Anson).

113. Market research conducted by Reed/Haldy/McIntosh, a reputable market research firm in the prescription drug field, likewise highlighted the effect of Eli Lilly's actions on Zeneca and Barr, the only two distributors of tamoxifen. The survey concluded that of the physicians surveyed 11 percent of their prescriptions for Evista are being written primarily for breast cancer prevention, as opposed to either for osteoporosis or for osteoporosis plus breast cancer, and that 35 percent of physicians have written at least some of their Evista prescriptions for the primary purpose of breast cancer prevention. Pl.'s Exh. 72 (Nolvadex Breast Cancer Prevention: Awareness, Trial and Usage Study by Reed/Haldy/McIntosh & Assocs. dated Feb. 15, 1999) at 31, 32; Pl.'s Exh. 80; Tr. at 477-79, 487-89 (McIntosh). This study does not, however, indicate that these prescribing patterns of physicians are the result of statement made by Eli Lilly, although the study is evidence that Evista competes with tamoxifen in the marketplace.

***31** 114. With respect to the impact of Eli Lilly's actions on the public at large, Dr. Lewis testified credibly that Eli Lilly's claims pose "a grave public health risk." Tr. at 345 (Lewis). Women at high risk of developing breast cancer may be placed on raloxifene, which has not yet been proven to reduce the risk of breast cancer, instead of on tamoxifen. Indeed, Eli Lilly's own witnesses have conceded that it would be dangerous if physicians relied on inaccurate information about prescription drugs conveyed by sales representatives. Tr. at 246-47 (Nicholson); Tr. at 858-59 (Torres).

II.

CONCLUSIONS OF LAW

1. This Court has jurisdiction over this action alleging violations of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), pursuant to 15 U.S.C. § 1121(a) and 28 U.S.C. § § 1331 and 1338(a).[FN9]

FN9. While the complaint asserted claims under the New York common law preventing unfair competition and New York General Business Law § § 349 and 350 preventing deceptive trade practices, those claims are not asserted as a basis for preliminary relief.

2. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

3. A party seeking a preliminary injunction bears the burden in Lanham Act cases, as in all others, of demonstrating (1) that it will suffer irreparable harm if the preliminary injunction is denied and (2) either (a) a likelihood of success on the merits, or (b) serious questions going to the merits to make them a fair ground for litigation and a balance of the equities tipping decidedly in the movant's favor. *See Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62 (2d Cir.1992). Zeneca and Barr have met this standard.

A. Zeneca and Barr are likely to succeed on the merits

1. *The governing Lanham Act standards*

4. Section 43(a) of the Lanham Act provides a civil remedy to those damaged by one who makes a "false or misleading representation of fact, which ... in commercial advertising or promotion, misrepresents the nature, characteristics [or] qualities ... of his or her or another person's goods, services or commercial activities." 15 U.S.C. § 1125(a)(1)(B). Because Section 43(a) is a "remedial statute," it is "broadly construed." *Gordon & Breach Science Publishers S.A. v. American Inst. of Physics*, 859 F.Supp. 1521, 1532 (S.D.N.Y.1994).

5. Courts have consistently held that oral statements by a company's sales representative concerning a product constitute "commercial advertising or promotion" under the Lanham Act. *See, e.g., Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 10 (7th Cir.1992); *Avon Prods., Inc. v. S.C. Johnson & Son, Inc.*, 984 F.Supp. 768, 772, 796 (S.D.N.Y.1997); *Pfizer, Inc. v. Miles, Inc.*, 868 F.Supp. 437, 449 (D.Conn.1994).

6. The burden of proving "literal falsity" varies depending on the nature of the challenged claim. When a defendant makes no mention of scientific tests or studies, the plaintiff must affirmatively prove that the statement is false. *See, e.g., Castrol, Inc.*, 977 F.2d at 63; *Glaxo Warner-Lambert OTC G.P. v.*

Johnson & Johnson Merck Consumer Pharmaceuticals Co., 935 F.Supp. 327, 329 (S.D.N.Y.1996). However, when a defendant's promotion implicitly or explicitly refers to tests or data-a so-called "establishment claim"-a plaintiff can satisfy its burden of proving literal falsity by demonstrating "that such tests are 'not sufficiently reliable to permit one to conclude with reasonable certainty that they established' the claim made." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir.1991) (citation omitted); *see also Castrol, Inc.*, 977 F.2d at 62. This standard of proof applies "[w]hen the ad relies on scientific studies, whether implicitly by making a claim while showing a graph or diagram, or explicitly, by stating, for example, 'that studies show.' " *Glaxo Warner-Lambert OTC G.P.*, 935 F.Supp. at 329; *see also Castrol, Inc.*, 977 F.2d at 63 (when defendant's advertisement "explicitly or implicitly represents that tests or studies prove its product superior, plaintiff satisfies its burden by showing that the tests did not establish the proposition for which they were cited").

***32** 7. A Lanham Act plaintiff seeking to enjoin an establishment claim can meet its burden by showing either (i) "that the tests were not sufficiently reliable to permit [the] conclusion" for which they are cited, or (ii) "that the tests, even if reliable, do not establish the proposition asserted by the defendant" and are thus "simply irrelevant." *Castrol, Inc.*, 977 F.2d at 63. Once a plaintiff has exposed a defendant's tests as irrelevant and/or unreliable, "relief may be granted without reference to the advertisements' impact" on consumers. *Pfizer*, 868 F.Supp. at 452 (quoting *Coca Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir.1982)).

2. *Eli Lilly is making two of the claims in question*

8. As set forth in the Court's Findings of Fact, there is abundant evidence that Eli Lilly representatives are systematically making claims that Evista has been proven to reduce the risk of breast cancer and that Evista has been proven comparable or superior to tamoxifen for the reduction of the risk of breast cancer. This evidence includes (i) the November and December sales representative verbatim scripts, (ii) Eli Lilly's call notes, (iii) the testimony of Eli Lilly's executives, (iv) eyewitness testimony, and (v) Eli Lilly's Richard Day research.

9. Although Eli Lilly and its witnesses effectively conceded that the company's representatives are making the claim that Evista has been proven to reduce the risk of breast cancer, Eli Lilly denied that it is making any improper comparisons to tamoxifen. However, as detailed in the Findings of Fact, the credible evidence shows that Eli Lilly is making the comparability claim versus tamoxifen.

10. The doctors' affidavits submitted by Eli Lilly are not sufficient to undermine the substantial evidence that Eli Lilly's sales representatives have been making the two claims in question. As noted in the first section of this Opinion, the affidavits are necessarily of less weight than the testimony of witnesses who were subject to cross-examination. Moreover, the affidavits themselves are ambiguous as to what Eli Lilly's sales representatives actually said to the doctors. Def.'s Exhs. T-4 through R-5.

11. The affidavits are also less reliable than the other evidence such as oral testimony and contemporaneous business records. The affidavits were made months after the fact of the visits and the visits themselves were quite short. Tr. at 798-99 (Torres).

12. The declarations are also narrowly written and ambiguously worded. Some declarations state that no comparison was made to tamoxifen or Nolvadex. *See, e.g.*, Def.'s Exhs. Z-4 (Decl. of Dr. James William Jackson), A-5 (Decl. of Dr. Frank Davis Jones), N-5 (Decl. of Lawrence Silver), R-5 (Decl. of Dr. John Yacoub). Others state only that no "direct" comparisons were made. *See, e.g.*, Def.'s Exhs. V-4 (Decl. of Dr. Donald Earle Courts), W-4 (Decl. of Dr. P. Timothy English), F-5 (Decl. of Dr. Francisco Munoz), I-5 (Decl. of Dr. P. Scott Pollack), L-5 (Decl. of Dr. Joanne M. Richards).

***33** 13. Finally, Eli Lilly could have had these doctors testify at the hearing on the preliminary injunction or taken their depositions, even by telephone, to provide the Court with the benefit of cross-examination. Eli Lilly failed to do so, however, and thus the affidavits of the doctors are entitled to less weight.[FN10]

FN10. Eli Lilly also maintains that the number of call note entries cited by Zeneca with respect to the tamoxifen comparisons are too small to rise to the level of a Lanham Act violation. However, courts have found that statements by sales representatives on a smaller number of occasions than that cited by Zeneca would violate the Lanham Act if those statements were determined to be

false. *See, e.g., Pfizer Inc. v. Miles, Inc.*, 868 F.Supp. 437, 460 (D.Conn.1994).

a. *Admissibility of Richard Day survey evidence*

14. Eli Lilly challenged the admissibility of market research conducted on its behalf by Richard Day. Zeneca offered that evidence, among other reasons, to corroborate the call notes and to prove that raloxifene and tamoxifen are competitors in the market.

15. The survey evidence will not be considered by the Court insofar as it is offered to corroborate the call notes. The defendant admitted at oral argument that its sales representatives have been making the "establishment" claim that Evista has been proven to reduce the risk of breast cancer. (Tr. of June 24, 1999 at 69, 74.) That admission, in addition to the call notes, verbatims, and other evidence, make it unnecessary to consider the survey evidence with respect to those claims. In addition, the evidence with respect to the alleged comparative claim that Evista is comparable or superior to tamoxifen for reducing the risk of breast cancer is quite strong based on the evidence detailed in the Findings of Fact, including the call notes and the verbatims. Thus there is no need to consider the survey evidence with respect to those claims. Finally, there is simply insufficient evidence that the defendant has been making the third claim-that Evista is indicated by the FDA for the prevention of breast cancer. The survey evidence in this case does not significantly support this claim by Zeneca and Barr and thus the survey evidence will not be considered with respect to that claim. However, the survey evidence is relevant to the issue of whether raloxifene and tamoxifen are competitors in the marketplace, as discussed below.

3. Eli Lilly's "establishment claim" that Evista has been proven to reduce the risk of breast cancer is *false*

a. *The claim is false*

16. Based on all the evidence adduced, Zeneca and Barr will likely succeed in proving that the MORE trial is "not sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the proposition for which [it was] cited"-namely, that Evista has been proven to reduce the risk of breast cancer. *Procter & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir.1984).

17. The FDA, as well as numerous other experts in the field of clinical oncology, have reviewed the breast cancer data from the MORE trial and reached the nearly unanimous conclusion that it does not prove that Evista reduces the incidence of breast cancer. The reasons for the unanimity of these organizations are described at length in the Findings of Fact. Most notably, the MORE protocol was not designed to determine whether Evista could be efficacious in reducing the risk of breast cancer. Accordingly, women were not selected for enrollment and once enrolled were not randomized between the raloxifene and placebo arms based on their degree of breast cancer risk. The protocol also did not require annual mammograms or breast physical exams, among other diagnostic deficiencies. Because of these and other critical flaws, the risk factors may have been imbalanced, the incidence of breast cancer may have been underdiagnosed and the results may yet turn out-as the CORE extension goes forward-to be a "false positive." Given the small number of invasive breast cancers that were diagnosed, a small number of additional invasive breast cancers in the raloxifene arm would have seriously compromised the results of the study.

***34** 18. Courts in this Circuit and elsewhere routinely enjoin claims of proven therapeutic efficacy on the ground that the underlying tests are irrelevant and/or unreliable to support them. *See, e.g., Castrol*, 977 F.2d at 63-64 (finding that tests "which proved faster oiling time, are irrelevant to [the] claim that [the defendant's] oil protects better" and thus the defendant's claim that tests proved that its product provided superior protection to engines was enjoined); *S.C. Johnson & Son, Inc. v. Clorox Co.*, 930 F.Supp. 753, 783 (E.D.N.Y.1996) (enjoining claim that "testing proves Combat SuperBait kills up to 98%" of household roaches because the tests were not reliable and did not measure what was being claimed because testing did not measure effectiveness of product in consumers' homes); *Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 906 F.Supp. 178, 182-83 (S.D.N.Y.1995) (enjoining claim that PEPCID AC controls acid "all day," in part because the defendant's studies related to night-time acid relief "[were] not relevant here" and because "[t]here was ... compelling evidence that [the defendant's studies] do not accurately measure acid control"), *aff'd*, 100 F.3d 943 (2d Cir.1996); *Pfizer, Inc.*, 868 F.Supp. at 457 (enjoining claim based on a study that lacked a

written protocol and scientific controls and noting that there was no discussion of the experimental methodology and controls or lack thereof).

b. *The FDA's findings are probative*

19. Eli Lilly has attempted to exclude and then to minimize the FDA's views on whether Evista has been proven to reduce the risk of breast cancer. [FN11] The FDA's views are not determinative and Zeneca and Barr are entitled to a preliminary injunction even without the views of the FDA. Nevertheless, it is appropriate to consider the views of the FDA on the highly regulated issue of drug efficacy.

FN11. The Court found in the first section of this Opinion that the FDA documents concerning Evista are admissible.

20. The FDA is the agency responsible for determining the safety and efficacy of prescription drugs in this country. *See* 21 U.S.C. § 393; Tr. at 740-41 (Cummings); Tr. at 1102 (Dere); Lippman Dep. Tr. at 84. Both parties' experts testified that FDA is a recognized authority and has expertise in assessing the results of clinical drug trials. Tr. at 427-29 (Carlson); Tr. at 740 (Cummings); Tr. at 1102 (Dere); Lippman Dep. Tr. at 84. Having reviewed all of the breast cancer data from the MORE trial and having met repeatedly with Eli Lilly's study investigators and scientists, the FDA found that MORE does not and cannot prove that Evista reduces the risk of breast cancer.

21. The fact that the FDA has not approved raloxifene for breast cancer risk reduction does not conclusively demonstrate that the defendant's claim that raloxifene has been proven to reduce the risk of breast cancer is literally false under the Lanham Act because "a Lanham Act plaintiff must prove that the defendant's efficacy claims are literally false, not simply that they fail to meet current federal licensing standards." *Avon Prods., Inc.*, 984 F.Supp. at 797. However, as a recognized expert in evaluating data from clinical trials, the FDA's conclusion as reflected in the Evista label and various FDA documents that "[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established" is persuasive evidence that Eli Lilly's claims to the contrary are untrue. Other courts have also found the FDA's expert conclusions to be relevant evidence in determining whether a party violated the Lanham Act. *See, e.g., SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co., Inc.*, 95 Civ. 7011, 95 Civ. 7688, 1996 WL 280810, at *13 (S.D .N.Y. May 24, 1996); *see also American Home Prods. v. Procter & Gamble*, 871 F.Supp. 739, 754 (D.N.J.1994) (expert's conclusion concerning efficacy of analgesic is "bolstered by the FDA's formal findings" concerning the product).

4. Eli Lilly's "establishment claim" that Evista has been proven comparable or superior to tamoxifen is *false*

***35** 22. The cases and arguments set forth above apply with equal force to the second establishment claim-that Evista has been proven comparable or superior to tamoxifen for reducing the risk of breast cancer. Because Evista has not been proven to reduce the risk of breast cancer, it necessarily has not been proven comparable or superior to tamoxifen in that regard.

23. Even if this Court had concluded that the MORE study was relevant and reliable as support for Eli Lilly's first claim, this comparative claim still would have to be enjoined. The experts at trial agreed that it is a fundamental principle of clinical testing that one cannot infer efficacy comparisons between two products when, as here, those products have not been tested against one another in a well-controlled head-to-head clinical study. Eli Lilly's own witnesses have confirmed this principle. Tr. at 180-81, 207-09 (Crenshaw); Tr. at 740 (Cummings); Lippman Dep. Tr. at 34-36. Other federal courts have previously indicated support for this principle. *See, e.g., Thompson Medical Co. v. Ciba-Geigy Corp.*, 643 F.Supp. 1190, 1195 (S.D.N.Y.1986) (noting that the defendant was previously enjoined from making any comparative efficacy claims "unless and until [it] has at least one adequate and well-controlled comparative clinical study which demonstrates such therapeutic advantage or superiority").

24. Eli Lilly has no data-flawed or otherwise-to "establish" the proposition that Evista has been proven comparable or superior to tamoxifen for the reduction of the risk of breast cancer. As Eli Lilly itself recognizes, that is one of the primary objectives of the upcoming STAR trial. Unless and until the STAR trial has been completed and proves that hypothesis, it is a clear violation of the Lanham Act for Eli Lilly to continue making this comparative establishment claim.

5. There is insufficient evidence that Eli Lilly is making the claim that Evista is indicated for the *prevention of breast cancer*

25. The parties agree that Evista is not indicated or approved by the FDA for reduction of the risk of breast cancer. Indeed, Eli Lilly has not even formally applied for such an indication. Zeneca and Barr argue that Eli Lilly is nevertheless promoting Evista as indicated by the FDA for the reduction of the risk of breast cancer, but there is insufficient evidence to support that allegation. As stated in the Court's Findings of Fact, few sales representatives' call notes provide any evidence that such a claim is being made. Moreover, no eyewitnesses testified that they have heard sales representatives making such a claim, no Eli Lilly verbatims instruct sales representatives to make such a claim, and no Eli Lilly witnesses supported the proposition that such a claim was being made. There is insufficient evidence that this claim is being made. Therefore, the Court cannot conclude that Zeneca and Barr are likely to succeed on this claim.

B. Zeneca and Barr have been irreparably harmed

***36** 26. As set forth above, Eli Lilly is making both comparative and non-comparative false establishment claims concerning Evista. As to either type of claim, Zeneca and Barr have demonstrated irreparable harm sufficient to warrant an injunction.

27. Once a plaintiff seeking to enjoin a false comparative claim demonstrates a likelihood of prevailing on the merits, irreparable injury is presumed when the defendant's "literally false ... comparative advertisement ... mentions plaintiff's product by name." *Castrol, Inc.*, 977 F.2d at 62. Moreover, when, as here, "the false or misleading advertising claims create a danger to public health, the presumption of irreparable harm is particularly appropriate." *McNeilab, Inc. v. American Home Prods. Corp.*, 675 F.Supp. 819, 826 (S.D.N.Y.1987), *aff'd*, 848 F.2d 34 (2d Cir.1988). Zeneca and Barr have satisfied the irreparable harm requirement with respect to Eli Lilly's false comparative claim that Evista has been proven comparable or superior to tamoxifen.

28. In the case of non-comparative false claims, the Lanham Act requires "only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising." *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir.1980); *see also Ortho Pharmaceutical Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 694 (2d Cir.1994) (noting that while a plaintiff in a Lanham Act case under § 1125(a) "must show more than a subjective belief that it will be damaged [by a false advertising claim], it need not demonstrate that it is in direct competition with the defendant or that it has definitely lost sales because of the defendant's advertisements" and that although injury and causation will not be presumed, "the type and quantity of proof required to show injury and causation has varied from one case to another depending on the particular circumstance") (internal quotation marks and citations omitted); *Coca-Cola Co.*, 690 F.2d at 316 (noting that a plaintiff in a Lanham Act case "must ... offer something more than a mere subjective belief that he is likely to be injured as a result of the false advertising ... he must submit proof which provides a reasonable basis for that belief") (internal citation omitted). To obtain injunctive relief, a Lanham Act plaintiff "need not even point to an actual loss or diversion of sales." *Coca-Cola Co.*, 690 F.2d at 316. Instead the plaintiff must show two things: (i) that the parties are competitors in the relevant market, and (ii) that there is a "logical causal connection between the alleged false advertising and its own sales position." *Johnson & Johnson*, 631 F.2d at 190-91. Zeneca and Barr have demonstrated both.

1. *Zeneca and Barr are competitors of Eli Lilly*

29. Eli Lilly maintains that even if it is making breast cancer reduction claims, it is not in competition with Zeneca or Barr because any Evista prescriptions written as a result of its breast cancer prevention claims are not coming at the expense of Zeneca or Barr; according to Eli Lilly, those prescriptions are likely written primarily for osteoporosis. This argument fails. It is clear that the parties are competitors.

***37** 30. First, by making claims that Evista has been proven or shown to reduce the risk of breast cancer, Eli Lilly has injected Evista into the emerging breast cancer prevention market. Since the only other product in that market is tamoxifen, Evista is clearly positioned by Eli Lilly in competition with tamoxifen, which is manufactured by Zeneca and distributed by Zeneca and Barr. *See Avon Prods.*, 984 F.Supp. at 775-78.

31. The call notes underscore this point. The notes

show that Eli Lilly is making blanket and categorical claims of breast cancer risk reduction, not merely claims directed to osteoporosis patients or coupled with osteoporosis claims. *See, e.g.,* Pl.'s Exh. 25, Entry 11/11/98-722809052 ("You can be assured Evista will not increase the risk [of breast cancer] and in every study showed there was a dcrease[d][sic] risk"); Entry 1/18/99-246801181 ("went into ev b. cancer data, told md he could let his women know they will be greater than 55rotected against b. cancer with evista"); Entry 1/26/99-848801056 ("I told him now he can actually say with confidence that Evista actually reduces the incidence of breast cancer"); Entry 2/8/99-240003187 ("point out the fact that there's no 'up-in-the-air' w/ Evista, because we know it reduces breast cancer").

32. These entries are echoed by the testimony of Denice Torres, who, as noted above, testified that in response to unsolicited questions, Eli Lilly representatives can tell physicians that "Evista[ ][has] been demonstrated to reduce the incidence of breast cancer" and that in studies up to three years, Evista reduces the risk of breast cancer by greater than 50 percent. Moreover, Ms. Torres testified that when an Eli Lilly representative states that Evista has been shown to reduce the incidence of breast cancer, the representative need not communicate any drawbacks or limitations, other than that Evista is not indicated for breast cancer risk reduction. Tr. at 217, 225-27, 229, 859-64 (Torres).

33. Second, the call notes show that Eli Lilly representatives are making direct comparisons to tamoxifen and, beyond that, are urging physicians to prescribe Evista instead of tamoxifen, thus squarely putting the two drugs in direct competition for the same prescriptions. *See, e.g.,* Pl.'s Exh. 23, Entry 10/5/98-578403397 ("evista 3 way-wanted to know re breast cancer data-told him the 60-80% reduction-he said what about tamox-said evista's data is better and doesn't increase risk for endometrium either."); Entry 10/12/98-169801604 ("he actually came over to me to talk about golf outing.....wow..... chatted a bit..... said the main thing that he learned was switching patients from tamoxifen to evista... great....."); Entry 11/03/98-244001904 ("he asked right away about BC, went into MORE and compared with Tamoxifen, we agreed that Evista is a much better choice"); Entry 11/16/98-422406095 ("He then wanted to know if I was saying-replace Tamoxifen with Evista. I said well, no FDA approval, but most of the doctors are already doing that, what will you do? He said Tamoxifen rep already came to detail him. I said, so far what you have is study on Tamox vs. placebo and Evista vs. placebo, although you can't really compare, Evista looks better and without the endo effects"); Entry 1/12/99-281202408 ("Evista first line ahead of tamox. for prevention"); Entry 2/17/99-360201058 ("Nolvadex rep had just left.....listened to her give entire tamox detail..... went right in and asked him..... 'Dr. Bill, why and where would you ever use Tamox over Evista?" '). These call notes are consistent with Eli Lilly's November 1998 verbatim, which instructed sales representatives to respond to doctors' questions by stating "these results [with respect to Evista's efficacy in reducing the risk of breast cancer] are similar to those for tamoxifen in women at high risk of breast cancer" and to make a favorable comparison to tamoxifen with respect to the safety profile of the drugs. Pl.'s Exh. 15 at EV 2609 327-28.

***38** 34. Third, and as Eli Lilly's Ms. Torres admitted, several internal Eli Lilly documents identify Zeneca as an Eli Lilly competitor. For example, a December 2, 1998 memorandum prepared by Ms. Torres captioned, "Maximizing the Breast Cancer Label Change," refers to an anticipated "competitive response," which Ms. Torres acknowledged was a reference to Zeneca, and goes on to note that "[w]e proactively and assertively position the P.I. change... not our competition." Pl.'s Exh. 16 at EV 2264 401-02; Tr. at 227-28 (Torres). Ms. Torres similarly wrote in a February 18, 1999 memorandum that "[t]here has been disturbing competitive activity involving misrepresentation of our NOV [notice of violation issued to Eli Lilly by FDA]. We are also planning on sharing competitive NOVs (Zeneca, Wyeth) with the Field to assure them we are also monitoring competitive activity ...." Pl.'s Exh. 49.

35. Fourth, Barr is plainly a competitor of Eli Lilly's. Not only does Barr distribute tamoxifen, with which Evista has been positioned to compete, but Barr also manufactures two products-estradiol and estropipate-that compete against Evista in the osteoporosis market. Tr. at 553 (Sawyer). Barr's products in the osteoporosis market give Barr an additional interest in being protected against false promotion of Evista for breast cancer risk reduction because such false promotion is reasonably likely to influence doctors' choices when prescribing a drug for the prevention of osteoporosis.

2. Zeneca and Barr have shown the requisite "causal *connection"*

36. Zeneca and Barr have likewise shown the

requisite causal connection between Eli Lilly's conduct and resulting harm to Zeneca and Barr.

37. There is no dispute that tamoxifen is the only drug approved for reduction of the risk of breast cancer. Ms. Anson confirmed that Zeneca is the only manufacturer of tamoxifen in the United States and "for every sale of a tamoxifen tablet in the market, Zeneca is therefore a beneficiary ...." Tr. at 53 (Anson). Barr distributes tamoxifen in its generic form. Thus, if doctors believe Eli Lilly's claim that Evista reduces the risk of breast cancer, Zeneca's and Barr's sales necessarily will be affected; any sale of Evista for breast cancer prevention or risk reduction is a lost sale of Zeneca's and may be a lost sale of Barr's.

38. Although it was not required to do so, Zeneca also presented survey evidence bolstering this point. A market research study conducted by Reed/Haldy/McIntosh, a reputable market research firm in the prescription drug field, concluded that of physicians surveyed, 11 percent of prescriptions for Evista are being written primarily for breast cancer prevention, as opposed to either for osteoporosis or for osteoporosis plus breast cancer, and that 35 percent of physicians have written at least some of their Evista prescriptions primarily for breast cancer prevention. Pl.'s Exhs. 72 & 80; Tr. at 477-79, 487-89 (McIntosh). The study does not prove that these prescriptions are being written because of statements made by Eli Lilly representatives. But since Eli Lilly executives acknowledge that the purpose of detailing these physicians is to persuade them to prescribe Eli Lilly's products, it is reasonable to conclude that at least some of these prescriptions resulted from Eli Lilly's false claims. *See Johnson & Johnson*, 631 F.2d at 190 ("The correct standard is whether it is likely that [defendant's] advertising has caused or will cause a loss of [plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales.").

***39** 39. The unique nature of the market in question is also relevant to the issue of whether Zeneca and Barr have demonstrated a causal connection between Eli Lilly's false claims about Evista and injury to Zeneca and Barr. *See Telebrands Corp. v. Wilton Indus., Inc.*, 983 F.Supp. 471, 475 (S.D.N.Y.1997) (irreparable harm will result from false advertising if "the materiality of the false statement coupled with the unique nature of the product" is likely to influence sales). Ms. Anson testified that there are no other drugs anywhere in the world, let alone in the United States, approved to reduce the incidence of breast cancer. Tr. at 47-49 (Anson). She also described this field as a "new marketplace." Tr. at 68-69 (Anson). Therefore, it would be even more difficult to quantify Zeneca or Barr's potential lost sales, particularly since tamoxifen sales cannot be broken down between the prevention and treatment indications. Tr. at 100 (Anson). In *Novo Nordisk A/S v. Becton Dickinson & Co.*, 997 F.Supp. 470, 473 (S.D.N.Y.1998), the court noted that a new entrant into an established market would have "a particularly difficult time proving money damages." Here, there is not only a new product but a new market itself, an even more complex situation.

3. *Zeneca's reputation and goodwill are jeopardized*

40. Injury to Zeneca's goodwill and reputation also supports the showing of irreparable harm. Courts in this Circuit have long held "[t]he likelihood of customer confusion, impairment of plaintiff's reputation and good will and probable diversion of customers, combined with the difficulty of proving actual monetary damages arising from Lanham Act injuries, justifies a presumption of irreparable injury once the violation has been established." *Upjohn Co. v. American Home Prods.*, 598 F.Supp. 550, 555 (S.D.N .Y.1984). Ms. Anson confirmed that there would be a "certain amount of loss of good will or injury to [Zeneca's] reputation from physicians as a result of [Eli Lilly's actions]." Tr. at 68-69 (Anson).

4. Eli Lilly's claim that Zeneca unreasonably delayed *is not meritorious*

41. As a final defense, Eli Lilly asserts that an injunction should not issue because Zeneca purportedly waited nearly nine months to commence this action. The Court rejects this argument.

42. Because of the public's overriding interest in preventing misleading advertising, the defense of laches is "sparingly applied" in Lanham Act cases. *American Home Prods. Corp. v. Johnson & Johnson*, 654 F.Supp. 568, 590-91 (S.D.N.Y.1987). This is particularly true when public health issues are implicated, as they are here. *See American Cyanamid Corp. v. Connaught Labs.*, 800 F.2d 306, 310 (2d Cir.1986) (noting in a trademark infringement case that "the potential consequences of confusion over medicinal products may be far more dire than of confusion over ordinary consumer products"); *Conopco, Inc. v. Campbell Soup Co.*, 95 F.3d 187,

194 (2d Cir.1996) (noting in a Lanham Act case that "the public's interest is especially significant when health and safety concerns are implicated" and that "public health and safety concerns may well overwhelm other considerations in the application of laches").

***40** 43. Here, there is no question that Zeneca has been vigilant in asserting its rights. Zeneca could not have filed this action before early November even if it had had sufficient evidence of Eli Lilly's misconduct by then. The FDA did not allow Zeneca to market tamoxifen for breast cancer risk reduction until late October 1998. It was not until early November, when Zeneca's marketing efforts began in earnest, that Zeneca and Eli Lilly became "competitors" in the breast cancer risk reduction market. Only then did Zeneca first have standing to sue under the Lanham Act. *See Johnson & Johnson*, 631 F.2d at 189 (only competitors, either direct or indirect, have standing to sue for Lanham Act violations).

44. Moreover, when Zeneca first received anecdotal evidence of Eli Lilly's misconduct last May, the Chief Executive Officer of Zeneca wrote to Eli Lilly's President complaining about what the sales representatives were saying about Evista. Pl.'s Exh. 1. Eli Lilly's President assured Zeneca at that time not only that Eli Lilly representatives would not make breast cancer prevention claims, but that any representatives who did so would be punished. Pl.'s Exh. 2. Zeneca cannot be faulted for relying on the word of Eli Lilly's president. Moreover, as Ms. Anson testified, the evidence of false claims began to escalate noticeably in November, after Zeneca was approved for breast cancer risk reduction, and in December, after the Evista label change. Tr. at 63-64 (Anson). Most of Eli Lilly's false statements date from late 1998, when, as the evidence shows, Eli Lilly representatives began to implement the revised November and December detailing scripts. Ms. Anson also explained that Zeneca acted on its suspicions and altered questions in its survey research to try to confirm the anecdotal proof it had gathered. Tr. at 64-65 (Anson). Zeneca obtained the results of the Reed/Haldy/McIntosh survey in January, and then promptly contacted its attorneys and filed this action shortly thereafter in February. Tr. at 65-66, 68 (Anson). *See Warner Lambert v. McCrory's*, 718 F.Supp. 389, 394-95 (D.N.J.1989) ("good faith preparation for litigation," including "commission [of] a study of possible consumer confusion," "should not be used to subsequently bar plaintiff from obtaining injunctive relief"). Thus, Zeneca did not delay unreasonably in bringing the current lawsuit.

45. The cases offered by Eli Lilly on the issue of delay confirm that delay in filing suit is not a bar to injunctive relief when, as here, "the plaintiff was making good faith efforts to investigate" the basis for its claims. *Krueger Int'l, Inc. v. Nightingale Inc.*, 915 F.Supp. 595, 613 (S.D.N.Y.1996). Unlike a typical false advertising case, where there is no dispute about what a defendant is claiming in television or radio commercials or in print advertisements, Zeneca faced the formidable hurdle of proving what a competitor's sales representatives were saying during in-person detail visits with doctors-a hurdle Zeneca has now cleared. In short, based on both the law and the facts, Zeneca did not unreasonably delay in bringing this action.

***41** 46. Moreover, there is no question that Barr did not unreasonably delay in this case. Barr first read in a trade publication that Eli Lilly was making claims that Evista reduces the risk of breast cancer in January 1999. It then learned in February 1999 that Zeneca had filed suit against Eli Lilly. Barr moved in March 1999 to intervene in this action. Tr. at 551-52 (Sawyer). Under these circumstances, there is no credible argument that Barr's claims against Eli Lilly are precluded by the doctrine of laches.

C. The equities weigh decisively in favor of an injunction

47. Since Zeneca and Barr have shown a strong likelihood of prevailing on the merits, it is unnecessary to reach the balance of equities. However, a preliminary injunction would be warranted under this standard also. Zeneca and Barr have plainly raised sufficiently serious questions going to the merits to make them fair ground for litigation. Equally clear, the balance of equities in this case tips decidedly in favor of granting an injunction.

48. As a result of more than two decades of research and testing by Zeneca as well as the investment of millions of dollars in research and development, tamoxifen is the only drug approved in the United States for the reduction of the risk of breast cancer. Tr. at 47-48, 68 (Anson). The evidence demonstrates that Eli Lilly's conduct threatens to erode the sales, goodwill, and physician and consumer confidence that Zeneca has developed over the years.

49. In contrast to the serious injury that will continue to befall Zeneca and Barr in the absence of an injunction, the comparative harm to Eli Lilly from an injunction is not great. Eli Lilly will merely be relegated to promoting Evista for its only approved use, prevention of osteoporosis. Eli Lilly can "assert no equitable interest in the perpetuation of an advertising campaign that is literally false." *Castrol, Inc. v. Pennzoil Co.*, 799 F.Supp. 424, 440 (D.N.J.1992), *aff'd*, 987 F.2d 939 (3d Cir.1993). Eli Lilly can continue, without violating the Lanham Act, to disseminate truthful information about Evista, including the results of the MORE study, and the existence of ongoing studies, so long as this information is in fact truthful.

50. The public interest also requires that an injunction issue. When an allegedly false claim pertains to a prescription drug, the public interest in receiving truthful information is particularly acute. Dr. Jerry Lewis testified that by telling physicians that Evista has been proven to reduce the risk of breast cancer Eli Lilly has created a "grave public health risk." Tr. at 345-46 (Lewis). And Eli Lilly's own witnesses have confirmed the obvious: it could be dangerous if a physician prescribes a drug erroneously believing that the drug could prevent cancer. Tr. at 247 (Nicholson). The evidence shows that doctors are prescribing Evista for the reduction of the risk of breast cancer. Although off-label prescribing-prescribing drugs for uses for which they are not indicated by the FDA-is not uncommon among physicians, Ans. ¶ 1, it would be dangerous if physicians off-label prescribed Evista for breast cancer prevention based on false information about whether Evista has been proven to reduce the risk of breast cancer. It is important to the public interest and to the patients involved that truthful information be provided.

D. The relief granted by the Court

***42** 51. "[C]ourts retain a great deal of flexibility when fashioning preliminary relief ...." *Abbott Labs.*, 971 F.2d at 23. The Court of Appeals for the Second Circuit has held that "the essence of equity jurisdiction has been the power to grant relief no broader than necessary to cure the effects of the harm caused by the violation." *Forschner Group, Inc. v. Arrow Trading Co.*, 124 F.3d 402, 406 (2d Cir.1997). Thus although "[a] district court has a wide discretion in framing an injunction in terms it deems reasonable to prevent wrongful conduct," *Forschner Group, Inc.*, 14 F.3d at 406 (internal quotation marks and citation omitted), the injunction framed by the district court must be "narrowly tailored to fit specific legal violations ... [and] should not impose unnecessary burdens on lawful activity." *Waldman Publ. Corp. v. Landoll, Inc.*, 43 F.3d 775, 785 (2d Cir.1994). Finally, a court's order of preliminary injunctive relief should be explicit and clear so that "those who must obey [it] will know what the court intends to forbid." *EFS Marketing, Inc. v. Russ Berrie & Co.*, 76 F.3d 487, 493 (2d Cir.1996) (internal citations and quotation marks omitted).

52. Applying the above standards to the Court's Findings of Fact and Conclusions of Law, the Court hereby preliminarily enjoins Eli Lilly from stating in its advertising or promotional activities that (i) Evista has been proven, shown, or demonstrated to reduce the risk of breast cancer, or that (ii) Evista has been proven comparable or superior to tamoxifen for the reduction of the risk of breast cancer. The Court will not enjoin Eli Lilly from stating that Evista has been approved by the FDA for the reduction of the risk of breast cancer because, although the claim is plainly false, there is insufficient evidence for the Court to conclude at this stage that Eli Lilly has been making such a claim and therefore Zeneca and Barr have failed to establish that they are entitled to a preliminary injunction on that claim.

53. The Court will not order the corrective advertising sought by Zeneca and Barr, although the Court recognizes that it has the discretion to order such relief. *See, e.g., Linotype Co. v. Varityper, Inc.*, 89 Civ. 4747, 1989 WL 94338, at *3 (S.D.N.Y. Aug. 4, 1989) (ordering corrective advertising, in non-establishment case, "to counteract the false impression that may have been placed by the [defendant's] ad in consumer's minds") (citation omitted). Such relief would be unnecessarily broad. The false information that Eli Lilly sales representatives have disseminated to physicians concerning raloxifene will be corrected by the revised detailing the sales representatives do after completing the training program ordered below.

54. The Court hereby orders defendant Eli Lilly to design and implement a training program for those Eli Lilly sales representatives who are responsible for detailing physicians about Evista, as well as oncology sales representatives and any other sales representatives who may reasonably be expected to encounter questions from physicians about Evista and its efficacy in reducing the risk of breast cancer. The training program should be designed to ensure that Eli Lilly's sales representatives are made aware of

and adhere to this Court's decision and order and do not make claims in the field that tamoxifen has been proven to reduce the risk of breast cancer or that it is comparable or superior to tamoxifen for the reduction of the risk of breast cancer. The training program should also explicitly inform sales representatives about the MORE data, the ongoing CORE and STAR trials, and the package insert statement that "[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established." *See Pfizer,* 808 F.Supp. at 461 (in addition to granting a preliminary injunction, Court ordered Pfizer to hold training sessions with its sales representatives to make them aware of the Court's finding that Pfizer had violated the Lanham Act by making false establishment claims about Pfizer's drug); *Valu Eng'g, Inc. v. Nolu Plastics, Inc.*, 732 F.Supp. 1024, 1026-27 (N.D.Cal.1990) (ordering defendant to send a letter to its sales representatives instructing them to stop making false advertising claims).

Conclusion

***43** At the present time, the evidence before the Court demonstrates that it is literally false for Eli Lilly to claim that raloxifene has been proven to reduce the risk of breast cancer or that raloxifene is comparable or superior to tamoxifen for that purpose. Such statements are false because, although the data from the MORE trial are promising, given the deficiencies in that trial, the MORE data are insufficient to support such claims, thus requiring further study of raloxifene before such claims can be made.

For the reasons explained above, the Court grants the motion of Zeneca and Barr for a preliminary injunction with respect to the establishment and comparative establishment claims and denies it with respect to the indication claim. A separate Order will be issued containing the Preliminary Injunction set out above.

SO ORDERED.

S.D.N.Y.,1999.
Zeneca Inc. v. Eli Lilly and Co.
Not Reported in F.Supp.2d, 1999 WL 509471 (S.D.N.Y.), 1999-2 Trade Cases P 72,603

END OF DOCUMENT

TAB 2

Westlaw.

Not Reported in F.Supp.
Not Reported in F.Supp., 1993 WL 603292 (N.D.Cal.), 29 U.S.P.Q.2d 1474
(Cite as: Not Reported in F.Supp.)

C
Creative Technology, Ltd. v. SRT, Inc.
N.D.Cal.,1993.

United States District Court, N.D. California.
CREATIVE TECHNOLOGY, LTD., Plaintiff(s),
v.
SRT, INC., dba Covox, Inc., Defendant(s).
No. C 93-3511 FMS.

Nov. 8, 1993.

Joel Linzner, Carla J. Shapreau, Crosby Heafey Roach & May, Oakland, CA, for plaintiff.
Richard P. Doyle, Jr., Flehr Hohbach Test Albritton & Herbert, San Francisco, CA, for defendant.

ORDER GRANTING PRELIMINARY INJUNCTION
FERN M. SMITH, District Judge.

INTRODUCTION

*1 Plaintiff (Creative Technology, Ltd.) seeks a preliminary injunction against defendant's (Covox, Inc.) use of the terms "Voice Blaster," "Fax Blaster" and "Phone Blaster" in connection with its merchandising of computer software products. Because the Court finds that plaintiff has shown that it is likely to succeed on the merits of its federal claim and has a strong chance of prevailing on its state law claim, and because the Court finds a likelihood of irreparable injury to Creative if injunctive relief is not granted, the Court hereby GRANTS plaintiff's motion for a preliminary injunction, as set forth below.

BACKGROUND

Plaintiff is an industry leader in the manufacture and marketing of computer sound cards, which are software products that add sound to personal computers. Plaintiff also manufactures video cards and other hardware and software products. In 1989, plaintiff released Sound Blaster,[FN1] a sound card that has since achieved great commercial success.

In March of this year defendant began marketing Voice Blaster, a voice recognition software product designed to be used in conjunction with Creative's Sound Blaster cards. Plaintiff wrote to defendant on March 12, 1993, demanding that defendant immediately cease using the name Voice Blaster for its products. On March 26, 1993, defendant responded to plaintiff's letter by refusing to halt its use of the mark Voice Blaster. Defendant maintained that plaintiff had no trademark in the term Sound Blaster and that the mark Voice Blaster was, in any event, not confusingly similar to Sound Blaster.[FN2]

On September 23, 1993, plaintiff brought suit against defendant for infringement and dilution under Lanham Act section 1125(a) and California Business and Professions Code section 14330. Plaintiff subsequently moved for a preliminary injunction against defendant's use of any mark incorporating the term "Blaster."

DISCUSSION

I. The Legal Standard

In order to prevail on its motion for a preliminary injunction, plaintiff must demonstrate either (1) a likelihood of success on the merits and the possibility of irreparable injury or (2) the existence of serious questions going to the merits and that the balance of hardships tips sharply in its favor. *See Metro Publishing, Ltd. v. San Jose Mercury News*, 987 F.2d 637 (9th Cir.1993).

Lanham Act section 1125(a) protects both registered and unregistered marks. *See* 15 U.S.C. section 1125 (West Supp.1993); *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 112 S.Ct. 2753 (1992); *New West v. NYM Company of California*, 595 F.2d 1194 (9th Cir.1979). To prevail on the merits of its Lanham Act claim plaintiff must prove both that it has a valid and protectible mark and that defendant's use of a similar mark is likely to cause confusion. *See Yarmuth-Dion, Inc. v. D'Ion Furs*, 835 F.2d 990 (2d Cir.1987). Plaintiff can satisfy the first prong of this test by showing either that its mark is inherently distinctive or that it has acquired secondary meaning in the marketplace. *Two Pesos*, 112 S.Ct at 2758. Secondary meaning is established by demonstrating that purchasers associate the mark with the producer

of the product, and not just with the product itself. *See, e.g., Yarmuth-Dion,* 835 F.2d at 993. The likelihood of confusion is evaluated according to an eight-part test. *See Metro Publishing,* 987 F.2d at 640. [FN3]

*2 The Business and Professions Code requires even less than the Lanham Act. To prevail on a claim for dilution under section 14330, plaintiff need show only that defendant's conduct is likely to injure plaintiff's business reputation or to dilute the distinctive quality of its mark. *See* Cal.Bus. and Prof.Code § 14330 (West Supp.1993); *Century 21 Real Estate Corp. v. Sandlin,* 846 F.2d 1175 (9th Cir.1988).

The majority of courts that have considered the issue have held that the Lanham Act does not preempt state anti-dilution statutes such as section 14330. *See* McCarthy, *McCarthy on Trademarks and Unfair Competition* § 22.02 [2] (3d ed. 1992). Plaintiff is entitled to a preliminary injunction if it can satisfy the *Metro Publishing* test with respect to either its federal or its state law claim.

II. The Strength of Plaintiff's Showing on the Merits

In evaluating whether plaintiff is entitled to a preliminary injunction, the Court must first consider the strength of plaintiff's showing with respect to the merits of its claims. *See Metro Publishing,* 987 F.2d 637 (9th Cir.1993). With respect to the Lanham Act claim the Court must consider to what extent plaintiff has established validity and infringement; with respect to the section 14330 claim, it must evaluate plaintiff's showing on the issues of dilution and injury.

Several factors are relevant to the determination of whether a mark has acquired secondary meaning: (1) the user's advertising expenditures; (2) consumer studies linking the name to the source; (3) sales success; (4) unsolicited media coverage of the product; (5) attempts to plagiarize the mark; and (6) length and exclusivity of the mark's use. *Yarmuth-Dion,* 835 F.2d at 993. Plaintiff has made strong showings on the first, third and fourth of these factors with respect to its Sound Blaster trademark. It is undisputed that Sound Blaster has been a commercial success and that the product is widely known in the industry. There is also direct evidence of secondary meaning, in the form of industry reports identifying Sound Blaster as a product of Creative. Plaintiff's evidence evinces a strong likelihood that plaintiff has acquired a protectible trademark in the term Sound Blaster. [FN4]

Plaintiff has also demonstrated a likelihood of confusion between plaintiff's Sound Blaster mark and defendant's Voice Blaster mark. Initially, plaintiff has made a prima facie showing that its mark is a strong one. Furthermore, the sight, sound and meaning of Sound Blaster and Voice Blaster are similar. There is a close nexus between defendant's Voice Blaster software and plaintiff's Sound Blaster products. Indeed, Voice Blaster is explicitly marketed for use with Sound Blaster. In a similar vein, plaintiff has shown that the marketing channels for the products converge and are often identical. There is some evidence of actual confusion by Covox's use of the Voice Blaster mark, and this confusion may be compounded by Creative's recent entry into the market for voice recognition software.[FN5] Finally, on the issue of intent, defendant's appropriation of the term "Blaster," a departure from its previous use of marks containing the term "Master," raises an inference that it intended to trade on plaintiff's good will. All of these factors combine to show that Covox's use of Voice Blaster is likely to cause confusion; thus, plaintiff has shown that it is apt to succeed on the merits of its Lanham Act claim.

*3 With respect to plaintiff's state law claim, the above factors raise a serious question as to whether defendant's use of the mark Voice Blaster is diluting the distinctive quality of plaintiff's Sound Blaster mark. In addition, plaintiff has offered evidence that Voice Blaster has been negatively received in the industry. Although this evidence is disputed by defendant's contrary evidence, it does tend to suggest that plaintiff may also prevail on its state law claim.

III. Irreparable Harm

Because plaintiff has shown that it is likely to succeed on its federal claim and that it has a strong case with respect to its state law claim, the Court must consider whether plaintiff has made a sufficient showing of irreparable harm to warrant the grant of a preliminary injunction. *See Metro Publishing,* 987 F.2d at 637 (9th Cir.1993). Plaintiff's delay in seeking the injunction does not necessarily bar the grant of preliminary relief. *See Ocean Garden, Inc. v. Marktrade Co.,* 953 F.2d 500 (9th Cir.1991).

In trademark actions, courts presume irreparable injury once the plaintiff has demonstrated a

likelihood of confusion. *Metro Publishing*, 987 F.2d at 640. In this case, the presumption of irreparable injury is reinforced by plaintiff's strong showing of good will in the mark Sound Blaster, which, if dissipated by defendant's continuing use of Voice Blaster, may be impossible to restore. While defendant may have begun to accrue good will in the mark Voice Blaster, its use of this mark is of recent origin, in contrast to plaintiff's longer standing use of Sound Blaster.

CONCLUSION

For the foregoing reasons, plaintiff's motion for a preliminary injunction is hereby GRANTED and a Preliminary Injunction is entered as follows:

Defendant, its officers, directors, employees, and agents, and all persons in active concert and participation with them who receive actual notice of this order by personal service or otherwise, are enjoined and restrained from manufacturing, converting, producing, promoting, marketing, distributing, offering for sale, or selling Voice Blaster, except pursuant to the following limitations:

1. Defendant is ordered to provide stickers, by December 1, 1993, to its distributors and retailers to be placed on Voice Blaster units already shipped. These stickers shall disclaim any association between Voice Blaster and Sound Blaster and Creative and shall be in a form approved by plaintiff.

2. Effective January 1, 1994, defendant is enjoined from using the mark Voice Blaster on its voice recognition software. In addition, all Voice Blaster units shipped from the date of this order until December 31, 1993 must be affixed with the stickers described in Paragraph 1 of this injunction, set out above.

3. Except as specifically allowed in this Order, defendant shall not release any products bearing the mark "Blaster", including but not limited to Fax Blaster or Phone Blaster.

4. Plaintiff is ordered to post a bond of $100,000.00 with the Clerk of this Court by November 12, 1993.

*4 A case management conference has been previously set for January 28, 1994, at 8:30 A.M. The parties shall file an appropriate joint statement as required by the Local Rules and this Court's standing orders.

SO ORDERED.

FN1. Plaintiff also markets products under the marks Midi Blaster, Port Blaster, Video Blaster and Wave Blaster.

FN2. Defendant is presently challenging plaintiff's attempt to register Sound Blaster on the Principal Register in an administrative proceeding before the Patent and Trademark Office (PTO). The basis of its opposition is its assertion that Sound Blaster is confusingly similar to Sound Master, a mark registered to the defendant. This Court need not stay its proceedings in the present action pending the outcome of the PTO proceedings, as the only consequence of those proceedings is the grant or denial of federal registration. Registration is not a prerequisite to suit for infringement under Lanham Act section 1125(a). *New West v. NYM Company of California*, 595 F.2d 1194 (9th Cir.1979).

FN3. The Ninth Circuit test for likelihood of confusion considers the following factors: (1) strength of the allegedly infringed mark; (2) proximity or relatedness of the goods; (3) similarity of the sight, sound, and meaning of the marks; (4) evidence of actual confusion; (5) degree to which the marketing channels converge; (6) type of goods and degree of care consumers are likely to exercise in purchasing them; (7) intent of the defendant in selecting the allegedly infringing mark; and (8) likelihood that the parties will expand their product lines. *Metro Publishing*, 987 F.2d at 640. This list is "neither exhaustive nor exclusive." *Id.* (citation omitted).

FN4. The Court finds it unnecessary to consider at this point whether plaintiff has established an a priori right to a "family" of marks containing the word "Blaster," as plaintiff's showing with respect to Sound Blaster alone is sufficiently strong to warrant a finding that plaintiff is apt to prevail at trial. *See Motorola, Inc. v. Griffiths Electronics, Inc.*, 317 F.2d 397 (C.C.P.A.1963); *Creamette Co. v. Merlino*, 299 F.2d 55 (9th Cir.1962).

FN5. In June, 1993, Creative commenced retail sales of its own voice recognition software, which it has called "VoiceAssist" pending the outcome of this litigation.

N.D.Cal.,1993.
Creative Technology, Ltd. v. SRT, Inc.
Not Reported in F.Supp., 1993 WL 603292 (N.D.Cal.), 29 U.S.P.Q.2d 1474

END OF DOCUMENT

TAB 3

LEXSEE 2006 U.S. DIST. LEXIS 33751

SYNOPSYS, INC., Plaintiff, v. MAGMA DESIGN AUTOMATION, Defendant. MAGMA DESIGN AUTOMATION, Counter Claimant, v. SYNOPSYS, INC., Counter Defendant.

C.A. No. 05-701 (GMS)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2006 U.S. Dist. LEXIS 33751; 64 Fed. R. Serv. 3d (Callaghan) 847; 2006-1 Trade Cas. (CCH) P75,320

May 25, 2006, Decided

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff filed a suit against defendant alleging three counts of patent infringement in violation of 35 U.S.C.S. § 271. Defendant answered and asserted seven counterclaims against plaintiff. Plaintiff moved to dismiss all but defendant's patent infringement counterclaim, moved to bifurcate defendant's antitrust counterclaims, and moved for a stay. Defendant sought leave to file an amended answer to add four additional infringement counterclaims.

OVERVIEW: In addition to its patent infringement counterclaim, defendant asserted monopolization and attempt to monopolize counterclaims under § 2 of the Sherman Act, 15 U.S.C.S. § 2; product disparagement and trade libel, in violation of § 43(a) of the Lanham Act, 15 U.S.C.S. § 1125(a); unfair competition under the Delaware Deceptive Trade Practices Act, Del. Code. Ann. tit. 6, § 2531 et seq. (1999) and common law; and a tortious interference with business relations counterclaim. The court found that defendant asserted actionable counterclaims. Its allegations, that plaintiff owned a 91 % share in two relevant markets and was acting anticompetitively by using the patent system and exclusive-dealing contracts to drive it out of business, were sufficient to state a claim under 15 U.S.C.S. § 2. Fed. R. Civ. P. 9(b) heightened pleading requirements did not apply to the Lanham Act counterclaims; defendant sufficiently met Fed. R. Civ. P. 8 requirements as to those counterclaims. The court declined to exercise its discretion under Fed. R. Civ. P. 42(b) to bifurcate the trial; bifurcating the antitrust claims was not necessary to prevent jury confusion and would not promote efficiency.

OUTCOME: The court denied plaintiff's motions. It granted defendant's motion for leave to amend its answer. The court ordered the parties to meet and confer regarding an amendment to the court's scheduling order.

COUNSEL: [*1] For Synopsys Inc., a Delaware corporation, Plaintiff: Karen Jacobs Louden, Morris, Nichols, Arsht & Tunnell, Wilmington, DE.; Leslie A. Polizoti, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE.

For Magma Design Automation, a Delaware corporation, Defendant: William J. Marsden, Jr., Fish & Richardson, P.C., Wilmington, DE.

For Magma Design Automation, a Delaware corporation, Counter Claimant: William J. Marsden, Jr., Fish & Richardson, P.C., Wilmington, DE.

JUDGES: Gregory M. Sleet, UNITED STATES DISTRICT JUDGE.

OPINION BY: Gregory M. Sleet

OPINION:

MEMORANDUM

I. INTRODUCTION

In the above-captioned action, Plaintiff and Counter Defendant Synopsys, Inc. ("Synopsys") alleges three counts of patent infringement in violation of 35 U.S.C.A. § 271 (2001 & Supp. 2005) against Defendant and Counter Claimant Magma Design Automation ("Magma"). In its first amended answer, Magma alleges against Synopsys one count of monopolization (Count I) and one count of attempted monopolization (Count II), both in violation of Section 2 of the Sherman Act, 15 U.S.C.A. § 2 (Supp. 2005), one count of product disparagement and trade libel (Count [*2] III) in violation of

Section 43(a) of the Lanham Act, 15 U.S.C.A. § 1125(a) (1998 & Supp. 2005), one count of statutory unfair competition (Count IV) in violation of the Delaware Deceptive Trade Practices Act, Del. Code. Ann. tit. 6, §§ 2531, *et seq.* (1999), one count of unfair competition (Count V) and one count of tortious interference with business relations (Count VI), both in violation of Delaware common law, and one count of patent infringement (Count VII). Presently before the court are Synopsys' motion to dismiss Counts I-VI of Magma's first amended answer (D.I. 9), Synopsys' motion to bifurcate and stay (D.I. 31), and Magma's motion for leave to file a second amended answer to include four additional patent infringement counterclaims (D.I. 50).

II. JURISDICTION

The court has subject matter jurisdiction pursuant to 28 U.S.C.A. §§ 1331, 1367 (1993).

III. BACKGROUND

According to the first amended answer, the patents at issue in this case relate to improvements in computer software used to design extremely complex integrated circuits. In general, such software translates a user's [*3] high-level description of the circuit he or she has designed and wishes to implement into a low-level description of the necessary components. This translation process is known as logic synthesis. The software then engages in a process known as physical design, in which the actual circuit layout and interconnections are determined. Eventually (after several steps irrelevant to this discussion) the newly-designed circuit is manufactured and ready for testing. The testing process typically requires the insertion of "scan chains" into the low-level description produced during logic synthesis. These scan chains consist of interconnected storage elements capable of being read from and written to during testing.

Magma alleges that Synopsys has a 91% share in both the logic-synthesis market and the scan-chain insertion market, which are monopolies Synopsys procured and maintains through anti-competitive conduct. More specifically, Magma contends that two of the patents asserted by Synopsys in this case were obtained by fraudulent means, and that Synopsys has attempted to create exclusive-dealing contracts with Magma's customers. Magma further alleges that Synopsys has engaged in a public [*4] campaign of disparagement by falsely claiming that Magma sells infringing products, and that Magma cannot afford to both defend itself in court and remain solvent.

IV. DISCUSSION

A. Motion to Dismiss

"When considering a Rule 12(b)(6) motion, [the court is] required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the plaintiff." *Evancho v. Fisher,* 423 F.3d 347, 350 (3d Cir. 2005). "A Rule 12(b)(6) motion should be granted 'if it appears to a certainty that no relief could be granted under any set of facts which could be proved.'" *Id.* at 351 (quoting *D.P. Enter. Inc. v. Bucks County Cmty. Coll.,* 725 F.2d 943, 944 (3d Cir. 1984)). "However, [the] court need not credit either 'bald assertions' or 'legal conclusions' in a complaint when deciding a motion to dismiss." *Evancho,* 423 F.3d at 351.

1. Sherman Act (Counts I & II)

Synopsys argues that Magma's monopolization and attempted monopolization claims under Section 2 of the Sherman Act should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) [*5] because they are unsupported by adequate factual allegations. In particular, Synopsys contends that the first amended answer fails to allege "antitrust injury," which, according to Synopsys, requires "harm to competition in the marketplace," and a causal connection between that harm and the anti-competitive activities.

In *Hosp. Bldg. Co. v. Trs. of Rex Hosp.,* the Supreme Court explained:

> "[A] complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson,* 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957) (footnote omitted). And in antitrust cases, where "the proof is largely in the hands of the alleged conspirators," *Poller v. Columbia Broadcasting,* 368 U.S. 464, 473, 82 S. Ct. 486, 7 L. Ed. 2d 458 (1962), dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly.

425 U.S. 738, 746, 96 S. Ct. 1848, 48 L. Ed. 2d 338 (1976). In this case, the clear import of Magma's allegations is that Synopsys, with a 91% share in both relevant markets, is acting anti-competitively by using the patent system and exclusive-dealing [*6] contracts to run a competitor, *i.e.,* Magma, out of business. If Synopsys is successful, Magma contends that there will be a decrease in competition because significant barriers to entry prevent would-be competitors from replacing the void left

by Magma. These allegations are sufficient to state a claim under Section 2 of the Sherman Act. *Gill v. Del. Park, L.L.C.*, 294 F. Supp. 2d 638, 644 (D. Del. Dec. 2, 2003) (explaining that "the anti-trust injury requirement is sufficiently pled where plaintiff alleges that he was excluded from participation in a particular market, and the result was a decrease in competition in that market").

2. Lanham Act (Count III)

Synopsys argues that Magma's Lanham Act claim is subject to the heightened pleading requirements of Rule 9(b), which provides that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). However, the "state of the law [is unsettled] as to whether Rule 9(b) was intended to incorporate claims brought under the Lanham Act." *H.H. Fluorescent Parts, Inc. v. DM Tech. & Energy, Inc.*, No. 04-1997, 2005 U.S. Dist. LEXIS 26699, [*7] at *13 (E.D. Pa. Nov. 3, 2005). If Count III is not subject to the heightened pleading requirements of Rule 9(b), then Magma's allegations need only satisfy the notice pleading requirements of Rule 8(a).

The purpose of "Rule 9(b) [is] to give defendants 'notice of the claims against them, provide[] an increased measure of protection for their reputations, and reduce[] the number of frivolous suits brought solely to extract settlements.'" *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 270 (3d Cir. 2006) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997)). Here, none of these purposes would be served by requiring Magma to satisfy the pleading requirements of Rule 9(b). The Lanham Act claim in this case is one of seven claims Magma brought in response to a suit originally filed by Synopsys. Thus, this is not a case in which the court must protect Synopsys against a "frivolous suit brought *solely* to extract a settlement." Moreover, the need to provide increased protection for Synopsys' reputation is not as crucial in this case because Count III was brought as a means of protecting Magma's reputation. [*8] Finally, even if Magma's pleadings do not specify the "who, when, and where" of Synopsys' allegedly damaging statements, that problem is easily cured in discovery. Therefore, the court holds that the heightened pleading requirements of Rule 9(b) are not applicable in this context.

"Under the Lanham Act a plaintiff must allege that: (1) defendant made false or misleading statements as to its product, or those of the plaintiff; (2) there was actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) the deception was material in that it is likely to influence purchasing decisions; (4) the advertised goods traveled in interstate commerce; and (5) there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc." *Enzo Life Scis., Inc. v. Digene Corp.*, 295 F. Supp. 2d 424, 427 (D. Del. Mar. 31, 2003). However, the required level of specificity with which each element must be pleaded is not high because Rule 8 only requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The first two elements [*9] are adequately pleaded by the allegation that Synopsys, knowing its patents were obtained by fraudulent means, engaged in a public campaign of disparagement by falsely claiming that Magma sells infringing products, and that Magma cannot afford to both defend itself in court and remaining solvent. The third element (materiality) and the fifth element (injury) are adequately pleaded by the allegation that Synopsys' campaign of disparagement has damaged Magma. And the fourth element (interstate commerce) is explicitly pleaded in paragraph 156 of the first amended answer. Thus, Magma has met the requirements of Rule 8 with regard to its Lanham Act claim.

3. State Law Claims (Counts IV, V & VI)

Synopsys argues that the court has no subject matter jurisdiction pursuant to 28 U.S.C.A. § 1367 over Magma's state law claims if Counts I-III are dismissed. However, because those counts will not be dismissed at this time, the court retains jurisdiction over Counts IV-VI.

B. Motion to Bifurcate and Stay

"The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate [*10] trial of any claim, cross-claim, counterclaim, or third-party claim . . . ." Fed. R. Civ. P. 42(b). "[T]he decision to bifurcate *vel non* is a matter to be decided on a case-by-case basis and must be subject to an informed discretion by the trial judge in each instance." *Lis v. Robert Packer Hosp.*, 579 F.2d 819, 824 (3d Cir. 1978).

Synopsys argues that the court should bifurcate the antitrust claims from the infringement claims because other courts routinely do so. This argument runs contrary to the guiding principle enunciated in *Lis*. There, the district court had simply followed its customary practice of separating the liability and damages phases in negligence cases without considering the unique circumstances of the negligence case at bar. On appeal, the Third Circuit held that this methodology ran afoul of Rule 42(b): "A general policy of a district judge bifurcating all negligence cases offends the philosophy that the decision must be made by a trial judge only as a result of an informed exercise of discretion *on the merits of each case*." *Lis*, 579 F.2d at 824 (emphasis added). Therefore, although [*11] the routine practice of other courts may indicate that "experience has demonstrated [the] worth"

of bifurcation in these circumstances, Fed. R. Civ. P. 42 advisory committee's note, the court's decision in this case will be guided first and foremost by the merits of this case.

With that principle in mind, the court is not convinced that bifurcation of the antitrust claims from the infringement claims is necessary to prevent jury confusion. In this court's experience, jurors are quite adept at comprehending and adhering to the instructions they are given, even in the most complex factual and legal scenarios. Therefore, the court will not pre-judge the yet-unnamed jurors by assuming they are unable to digest the facts and law in this case. Moreover, the court is confident that the experienced attorneys handling this case will craft cogent presentations to aid the jury in this process. The court is further unpersuaded by Synopsys' contention that bifurcation would serve the interest efficiency. Magma's antitrust claims are based in part on the allegation that Synopsys fraudulently-obtained two of its patents and asserted them against Magma in [*12] violation of Section 2 of the Sherman Act. Synopsys' alleged fraud is also a centerpiece of Magma's invalidity claims. Thus, were the court to bifurcate, the evidentiary presentation in one case would likely be substantially duplicative of the evidentiary presentation in the other. In addition, bifurcation would likely create further duplication of evidence because both juries would need to be educated in the same relevant technology. Accordingly, the court concludes that neither jury confusion nor efficiency weigh in favor of bifurcating the antitrust claims from the infringement claims.

Synopsys also argues that the antitrust claims should be stayed until the infringement claims are resolved mainly because resolution of the infringement claims could streamline subsequent adjudication of the antitrust claims. Assuming *arguendo* that the litigation could be streamlined in this way, it is telling that Synopsys does not propose to shorten the number of days allocated for trial in the event that a stay is granted. Thus, even if the court stays the antitrust claims, the minimum amount of time allocated to try this case does not decrease. Consequently, it appears that a stay only has [*13] the potential to consume *more* of this court's valuable time. Therefore, the court will not stay the antitrust portion of this action.

For similar reasons, the court also declines to stay Synopsys' infringement claims pending re-examination by the PTO. The validity of the asserted patents will be litigated regardless of whether a stay is granted because that issue is relevant to Magma's Sherman Act claims. The most efficient course of action, then, is to also litigate infringement in order to capitalize on the jury's understanding of the relevant technology. Thus, the court will deny Synopsys' motion in its entirety.

C. Motion to Amend

Pursuant to the court's scheduling order of December 28, 2005, the deadline for amended pleadings is March 24, 2006. On that date -- March 24 -- Magma timely filed a motion for leave to amend its first amended answer to include four additional counterclaims for patent infringement. "[A] party may amend the party's pleading only by leave of court or by written consent of the adverse party; and leave shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). "In the absence of any apparent [*14] or declared reason -- such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. -- the leave sought should, as the rules require, be 'freely given.'" *Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962).

Synopsys' primary basis for opposing Magma's motion is that fact discovery is scheduled to close on September 26, 2006, thus giving the parties less than six months to both conclude discovery on the claims already in the case, and to conduct full discovery on the four additional patent infringement claims. However, trial in this case is not scheduled to begin until June 11,2007, which should give the parties ample time to conduct additional discovery beyond September 26 without disturbing the trial date. Thus, the court will grant the motion and order the parties to meet and confer regarding an amendment to the court's scheduling order. n1

n1 Synopsys claims that Magma's four additional patents are not sufficiently similar to the technology at issue in this case to justify their inclusion. However, Synopsys merely proposes that "a review of the patents quickly reveals that there is little similarity" among the patents. (D.I. 63 at 8.) In this lay court's opinion, a review of the patents quickly reveals enough similarity among the patents to justify including them in this lawsuit.

[*15]

V. CONCLUSION

For the reasons stated, the court will deny the motion to dismiss, deny the motion to bifurcate and stay, and grant the motion to amend. The court will further order the parties to meet and confer to regarding an amendment to the court's scheduling order.

Dated: May 25, 2006

/s/ Gregory M. Sleet

UNITED STATES DISTRICT JUDGE

ORDER

IT IS HEREBY ORDERED THAT:

1. The motion to dismiss (D.I. 9) be DENIED;

2. The motion to bifurcate and stay (D.I. 31) be DENIED;

3. The motion to amend (D.I. 50) be GRANTED; and

4. The parties MEET and CONFER regarding the scheduling order.

Dated: May 25, 2006

/s/ Gregory M. Sleet

UNITED STATES DISTRICT JUDGE